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114TH CONGRESS
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COMMITTEE PRINT

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COMPILATION OF ACTIVITIES OF THE SELECT INVESTIGATIVE PANEL OF THE COMMITTEE ON ENERGY AND COMMERCE

FINAL REPORT

HEARING: BIOETHICS AND FETAL TISSUE

March 2, 2016

HEARING: THE PRICING OF FETAL TISSUE

April 20, 2016

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HEARING APRIL 20, 2016

WITNESSES

SUBMITTED MATERIAL

H. Res. 461

In the House of Representatives, U. S.,

October 7, 2015.

Resolved, That there is hereby established a Select Investigative Panel of the Committee on Energy and Commerce (hereinafter "select panel").

SEC. 2. (a) The select panel shall be composed of not more than 14 Members, Delegates, or the Resident Commissioner appointed by the Speaker, of whom not more than six shall be appointed on the recommendation of the minority leader. Any vacancy in the select panel shall be filled in the same manner as the original appointment.

(b) Each member appointed to the select panel shall be treated as though a member of the Committee on Energy and Commerce for purposes of the select panel.

(c) No member may serve on the select panel in an ex officio capacity.

(d) The Speaker shall designate as chair of the select panel a member elected to the Committee on Energy and Commerce.

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SEC. 3. (a) The select panel is authorized and directed to conduct a full and complete investigation and study and issue a final report of its findings (and such interim reports as it may deem necessary) regarding—

(1) medical procedures and business practices used by entities involved in fetal tissue procurement;

(2) any other relevant matters with respect to fetal tissue procurement;

(3) Federal funding and support for abortion providers;

(4) the practices of providers of second and third trimester abortions, including partial birth abortion and procedures that may lead to a child born alive as a result of an attempted abortion;

(5) medical procedures for the care of a child born alive as a result of an attempted abortion; and

(6) any changes in law or regulation necessary as a result of any findings made under this subsection.

(b) The chair of the Committee on Energy and Commerce shall cause any such report to be printed and made publicly available in electronic form.

SEC. 4. Rule XI and the rules of the Committee on Energy and Commerce shall apply to the select panel in the same manner as a subcommittee except as follows:

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(1) The chair of the select panel, consistent with the notification, consultation, and reporting requirements of rule 16 of the rules of the Committee on Energy and Commerce, may authorize and issue subpoenas pursuant to clause 2(m) of rule XI in the investigation and study conducted pursuant to section 3, including for the purpose of taking depositions.

(2) The chair of the select panel, upon consultation with the ranking minority member, may order the taking of depositions, under oath and pursuant to notice or subpoena, by a member of the select panel or a counsel of the select panel. Such depositions shall be governed by the regulations issued by the chair of the Committee on Rules pursuant to section 3(b)(2) of House Resolution 5, One Hundred Fourteenth Congress, and printed in the Congressional Record. The select panel shall be deemed to be a committee for purposes of such regulations.

(3) The chair of the select panel may, after consultation with the ranking minority member, recognize—

(A) members of the select panel to question a witness for periods longer than five minutes as though pursuant to clause 2(j)(2)(B) of rule XI; and

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(B) staff of the select panel to question a witness as though pursuant to clause 2(j)(2)(C) of rule XI.

SEC. 5. Service on the select panel shall not count against the limitations in clause 5(b)(2)(A) of rule X.

SEC. 6. The select panel shall cease to exist 30 days after filing the final report required under section 3.

Attest:

Clerk.

Final Report

Select Investigative Panel

of the Energy & Commerce Committee
December 30, 2016

Select Investigative Panel

of the Energy & Commerce Committee

Select Investigative Panel

Final Report

Rep. Marsha Blackburn (TN-7)
Chairman

Rep. Joseph Pitts (PA-16)
Rep. Diane Black (TN-6)
Rep. Larry Bucshon (IN-8)
Rep. Sean Duffy (WI-7)
Rep. Andy Harris (MD-1)
Rep. Vicky Hartzler (MO-4)
Rep. Mia Love (UT-4)

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Executive Summaries

I. Congress Establishes the Select Investigative Panel

- David Daleiden, an investigative journalist, released undercover videos beginning in July 2015, recorded while posing as the head of a company interested in the fetal tissue procurement business. In numerous meetings with abortion providers and companies involved in the transfer of fetal tissue, Daleiden recorded doctors, executives, and staff-level employees discussing various aspects of the fetal tissue procurement industry.

- The videos and other materials that Daleiden acquired detailed the relationship between fetal tissue procurement companies, including Advanced Bioscience Resources, DaVinci Biologics, and StemExpress, and several abortion clinics.

- The exposé followed an investigation Daleiden conducted through a not-for-profit group he founded, the Center for Medical Progress (CMP). CMP's first project, the "Human Capital" investigation, took almost three years. Working under the guise of a tissue procurement business in order to gain access to the top levels of Planned Parenthood, Daleiden, Susan Merritt, and other activists recorded numerous videos documenting conversations in which Planned Parenthood executives discussed the procurement of fetal tissue from aborted fetuses.

- The investigation culminated with the release of eleven videos documenting the practices of local abortion clinics and groups affiliated with the fetal tissue procurement industry. Daleiden and his colleagues filmed hundreds of hours of meetings and conversations. According to the *Washington Post*, they filmed 500 hours of footage at two conferences alone.

- Multiple clips show abortion providers and executives admitting that their fetal tissue procurement agreements are profitable for clinics and help keep their bottom line healthy. Multiple clips also show them admitting that they sometimes changed the abortion procedure in order to obtain a more intact specimen, and some use the illegal partial birth abortion procedure.

- Planned Parenthood Federation of America (PPFA) also revealed that they intentionally had not set a policy about "remuneration" for fetal tissue because "the headlines would be a disaster." While the organization's executives told affiliates to "think, 'New York Times headline'" if this went badly, at the end of the day, they thought "[selling fetal tissue] is a good idea."

- Congress responded to the videos by holding hearings and initiating investigations. The Energy and Commerce Subcommittee on Oversight and Investigations initiated an investigation of fetal tissue transfers. The Committee on Oversight and Government Reform and the Judiciary Committee conducted hearings and also initiated investigations.

- On October 7, 2015, Rep. Virginia Foxx (NC-5) managed the floor debate for H. Res. 461, a proposal for a centralized and comprehensive congressional investigation. During debate, Rep. Mimi Walters (CA-45) noted, "This resolution would create a select panel to investigate a number of claims related to Planned Parenthood's activities involving abortion and fetal tissue procurement. Like many Americans, I was horrified by the recent videos which depicted Planned Parenthood employees callously discussing the trafficking and sale of aborted babies' tissues and organs." Rep. Marsha Blackburn (TN-7) summarized:

> I want to clearly state this is about getting answers of how we treat and protect life in this country. The select panel will act to centralize the investigations that are at the Energy and Commerce Committee, Judiciary and Oversight Committees, and bring it all under one umbrella. Over the past several weeks, we have had lots of serious questions. They are troubling questions that have been asked. I think that the investigations we have had have raised a lot of those questions. It is imperative that we centralize these operations and bring it together under one umbrella.

- Congress passed H. Res. 461 by a recorded vote of 242 yeas and 184 nays. Rep. Blackburn was named Chairman of the Panel.

- The Panel did not design its investigation to prove or disprove the credibility of tapes released by the Center for Medical Progress (CMP); however, the Panel viewed the videos as a series of serious claims made by a citizen advocacy group.

- The Panel's investigation identified four business models involving fetal tissue procurement:

    - *The Middleman Model.* This model comprises a middleman and tissue procurer who obtains tissue directly from a source such as an abortion clinic or hospital and then transfers the tissue to a customer, usually a university researcher.

    - *The University/Clinic Model.* This model comprises a particular university that has formed a close relationship with a nearby abortion clinic and regularly acquires tissue from that clinic for research purposes.

    - *The Biotech Company/Clinic Model.* This model comprises a close relationship between a particular biotech company and one or more nearby clinics.

    - *The Late-Term Clinic Model.* This model is of particular concern due to the intersection of late-term abortions, the potential for live births during the abortion procedure, and the transfer of tissues or whole cadavers from that clinic to research entities.

- The Panel designed an investigative work plan based on these business models.

II. Applicable Laws, Regulations, and Commissions

- Federal and state laws germane to the Panel's investigation can be grouped into four broad categories, with some overlap: (1) laws protecting human research subjects and patient privacy; (2) laws regulating anatomical gifts for transplantation, therapy, research, and education; (3) laws protecting late-term and born-alive infants; and (4) laws pertaining to public funding for fetal tissue research and abortion providers.

A. Laws protecting human research subjects and patient privacy

- Laws protecting human research subjects and privacy are rooted in the principles set forth in the Belmont Report.

- Research subjects must be respected as autonomous persons, researchers must adhere to the Hippocratic ideal, and the benefits of research must outweigh the risks to human research subjects.

- The Panel examined the legal and ethical importance of informed consent under the Belmont principles. During the Panel's hearing on *Bioethics and Fetal Tissue*. Rep. Vicky Hartzler (MO-4) addressed an important statement in the Belmont Report regarding informed consent—that "inducements [to consent] that would ordinarily be acceptable may become undue influences if the [research] subject is especially vulnerable."

- Mrs. Hartzler asked an ethics expert if a form known to be widely used by abortion clinics to obtain a mother's consent to donate fetal tissue complied with "HHS's mandate against inducement." The form stated that "[r]esearch using the blood from pregnant women and tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."

- The witness agreed that this was an important question, because the "idea of the promise of cures" found in the form was a "very powerful motivator." The witness also indicated that the "consent" form was deficient in other ways: "The concern I have is that the standards that we have typically for fetal tissue donation are just absent here. And so in addition to the voluntariness, there is just the thoroughness of the consent [that] seems to be missing in this form."

- The testimony provided by witnesses invited by both the majority and minority raised concerns that the principles embodied in the Belmont Report, and later incorporated into

federal regulations, are not being followed by abortion providers seeking consent for the donation of human fetal tissue.

- In response to the Belmont Report, HHS and the FDA significantly revised their human subjects regulations in 1981. The Common Rule applies to research projects that receive funding from federal agencies, requiring three steps to be fulfilled before the research can take place: 1) the human subject must give informed consent; 2) an Institutional Review Board (IRB) must review the proposed research project; and 3) the institution conducting the research must file an assurance of compliance with the federal agency that is providing the funding.

- The Panel's investigation revealed evidence that the IRB process used by some fetal tissue procurement businesses is often grossly insufficient. For instance, on March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of federal regulations, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval. BioMed IRB's executive director informed the Panel on April 4, 2016, that in regards to those records, "there are none." This is an apparent direct violation of federal regulations.

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule (Privacy Rule) protects all individually identifiable health information held or transmitted by a covered entity or its business associate and calls this information protected health information (PHI). PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual, and includes demographic data relating to an individual's health condition, provision of health care, or payment for the provision of health care to the individual.

- The Panel's investigation indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. These violations occurred when the abortion clinics disclosed patients' individually identifiable health information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

B. Laws regulating anatomical gifts for transplantation, therapy, research, and education

- Laws regulating anatomical gifts are also heavily centered on the need for informed consent. Additionally, federal and many state laws explicitly prohibit the sale of human body parts.

- The National Organ Transplant Act (NOTA) provides that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. . . . Any person who violates [] this section shall be fined not more than $50,000 or

imprisoned not more than five years, or both." The term "human organ" is defined to include fetal organs and subparts of organs.

- The Uniform Anatomical Gift Act (UAGA), a model statute first available in 1968 and most recently amended in 2009, was written to facilitate organ donation for transplantation, therapy, research, and education by ensuring that state laws are consistent across the country.

- The UAGA, adopted in every state in some form, includes stillborn babies and fetuses in the definition of "decedent" for purposes of obtaining consent from a relative before the deceased infant's body is donated for experimentation or transplantation. In the UAGA's official notes, the drafters explain that the inclusion of stillborn babies and fetuses ensures that they "receive the statutory protections conferred by this [act]; namely that their bodies or parts cannot be used for transplantation, therapy, research, or education without the *same appropriate consents* afforded other prospective donors."

- The Panel learned that the University of New Mexico (UNM) and the late-term abortion clinic Southwestern Women's Options (SWWO) have an extensive history in which SWWO provided fetal tissue to UNM researchers. SWWO's provision and UNM's acquisition of and research using aborted infant remains appear to violate New Mexico's anatomical gift act, the Spradling Act.

- Under the NIH Revitalization Act of 1993, it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

- Laws regulating the donation of human organs, including human fetal organs, are relevant for the Panel's investigation, given the possibility that both tissue procurement businesses (TPB's) and abortion providers are profiting from fetal tissue procurement.

- During the Panel's April 20, 2016 hearing, *The Pricing of Fetal Tissue*, Panel members asked witnesses to examine evidence that payments paid by customers to a TPB for fetal tissue exceeded costs incurred by the business by a factor of 300 to 700 percent. Further, the evidence *did not* demonstrate that in many instances the "compensated" abortion clinics incurred any actual costs.

C. Laws protecting late-term and born-alive infants

- Laws protecting late-term unborn infants and infants born alive during abortion procedures recognize that the "right to an abortion" does not equal the right to a dead child. Federal laws prohibit a specific abortion procedure that occurs seconds before livebirth, and explicitly provide that infants born alive enjoy all of the constitutional rights available to other Americans.

- During the Panel's investigation, staff reviewed tissue procurement notes, email exchanges among researchers, TPB's and abortion clinics, invoices, and more—all indicating that researchers want fetal tissue from late-gestation infants that has not been tainted by feticidal agents (*e.g.*, digoxin).

- The Panel also learned that abortion providers may modify abortion procedures, in apparent violation of the law, to increase the odds of getting an intact infant cadaver (*e.g.*, increase the number of laminaria placed in a patient's cervix to achieve greater dilation). Clearly, these factors increase the likelihood that unborn infants are born alive during late second-trimester abortions, and raise the question whether these infants' civil rights are recognized by abortion providers.

D. Laws pertaining to public funding for fetal tissue research and abortion providers

- Finally, laws pertaining to public funding for fetal tissue research and abortion providers need reforming. In particular, while federal law contains numerous restrictions on public funding for abortion, abortion providers receive millions of federal dollars ostensibly for other purposes.

- Government investigations and whistleblower testimonies have revealed that abortion providers often fail to separate public funding from abortion-related costs.

- The Charlotte Lozier Institute and Alliance Defending Freedom have documented that—based on 51 known external audits or other reviews of Planned Parenthood affiliates' financial data and practices, and 61 federal audits of state family planning programs by HHS-OIG—Planned Parenthood affiliates have overbilled $132.4 million in Medicaid and other healthcare funding programs. These audit results are troubling, given their limitations in scope, detail, and timeframe; in fact, of 57 U.S. Planned Parenthood affiliates, only 19 have been audited.

- The Obama administration has denied or threatened to deny federal Medicaid funding to states that have attempted to withhold Medicaid reimbursement from abortion providers. Further, the Seventh and Ninth Circuits have interpreted Medicaid's "free choice of provider" provision—guaranteeing Medicaid recipients' freedom to choose their family planning providers—as a legal impediment to prohibiting abortion providers from receiving federal Medicaid funding.

- However, in *Planned Parenthood v. Indiana* the Seventh Circuit *upheld* Indiana's prohibition on abortion providers receiving funding through the federal Disease Intervention Services agency (DIS), for the diagnosis and monitoring of sexually transmitted diseases. The Seventh Circuit explained that the key difference between the provision upheld and the provision struck down was that the DIS program did *not* have a federal statutory limitation (similar to Medicaid's "free choice of provider" provision) on how states could determine eligibility.

- Title X is the only federal grant program dedicated solely to providing family planning and related preventive care and is viewed as setting the standard for publicly funded family planning services. Priority is given to low-income families. Title X provides that "none of the funds appropriated ... shall be used in programs where abortion is a method of family planning." Public and private entities may obtain grants.

- Since 2011, numerous states have enacted laws requiring subrecipients of Title X funds to provide comprehensive healthcare to patients and/or refrain from performing abortions. In response, the federal government is actively circumventing the Title X prioritization laws in at least eight states by directly contracting with private entities such as Planned Parenthood.

- Further, on Sept. 9, 2016, HHS issued a proposed rule stating that "[n]o recipient making sub awards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons unrelated to its ability to provide services effectively." In the proposed rule background, HHS states that "13 states have placed restrictions on or eliminated sub awards with specific types of providers. . . ."

Chapter III. Panel Hearings

- The Panel held two public hearings to examine critical issues within its jurisdiction. In the first hearing on *Bioethics and Fetal Tissue*, the Panel noted that there have been several government-sponsored discussions on bioethics, but none directly on the transfer of fetal tissue since the 1980s.

- The hearing revealed substantial concern about the consent process for the donation of human fetal tissue used by abortion clinics and tissue procurement businesses (TPBs). Evidence revealed that self-interested staff, whose pay depends on the numbers of specimens donated, were assigned to obtain consent from patients.

- Additional evidence showed that tissue technicians and the abortion clinics violated the patient's privacy rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Still other evidence revealed that some TPBs misrepresented that the consent forms and methods of tissue harvesting comply with federal regulations regarding Institutional Review Boards (IRBs). This evidence points toward conduct focused on profit and not on patient welfare.

- The Panel's next hearing, *The Pricing of Fetal Tissue*, sought the judgment of seasoned federal prosecutors to compare the federal statute prohibiting profit from fetal tissue sales with the first tranche of materials from the investigation.

- Two former U.S. attorneys and a senior federal litigator agreed that based on the materials presented to them, they would open a case against a TPB. The former

prosecutors also suggested that accounting and bank records would be critical to understanding whether there was a violation of federal law. Minority witnesses agreed with this approach and urged the panel to obtain such records.

Chapter IV. The Criminal Referrals

The Select Investigative Panel has made numerous criminal and regulatory referrals and investigations are underway around the nation.

1) The Panel learned that StemExpress and certain abortion clinics may have violated the HIPAA privacy rights of vulnerable women for the sole purpose of increasing the harvesting of fetal tissue to make money. Referred to the U.S. Department of Health and Human Services.

2) The Panel uncovered evidence showing that StemExpress may have violated federal regulations governing Institutional Review Boards (IRBs). Referred to the U.S. Department of Health and Human Services.

3) The Panel discovered that the University of New Mexico may have been violating its state's Anatomical Gift Act by receiving tissue from a late-term abortion clinic (Southwestern Women's Options). Referred to the Attorney General of New Mexico.

4 & 5) The Panel conducted a forensic accounting analysis of StemExpress' limited production and determined that it may have been profiting from the sale of baby body parts. Referral sent to El Dorado, California District Attorney, and the U.S. Department of Justice.

6) The Panel discovered that an abortion clinic in Arkansas may have violated the law when it sent tissue to StemExpress. Referred to the Attorney General of Arkansas.

7) The Panel discovered that DV Biologics, another tissue procurement company, may have been profiting from the sale of fetal tissue, and was not collecting California sales tax from purchasers of the baby body parts. The Orange County District Attorney has filed a lawsuit and the Panel sent a supplemental referral.

8) The Panel learned that Advanced Bioscience Resources appeared to have made a profit when it sold tissue to various universities. Referred to the District Attorney for Riverside County, California.

9) The Panel discovered that an abortion clinic in Florida, at least in part through its relationship with StemExpress, may have violated various provisions of federal and state law by profiting from the sale of fetal tissue. Referred to the Attorney General of Florida.

10) The Panel learned that Planned Parenthood Gulf Coast may have violated both Texas law and U.S. law when it sold fetal tissue to the University of Texas. Referred to the Texas Attorney General.

11 & 12) The Panel has uncovered evidence from former employees and a patient of a late-term abortionist in Texas alleging numerous violations of federal and state law at one or more of the practitioner's clinics. The allegations include eyewitness accounts of the doctor killing infants who show signs of life both when partially outside the birth canal, in violation of the Partial-Birth Abortion Ban Act, and after they are completely outside the birth canal, in violation of the Born-Alive Infants Protection Act and Texas murder statutes. Referred to the Texas Attorney General, and the U.S. Department of Justice.

13) The Panel has discovered information that StemExpress may have destroyed documents that were the subject of congressional inquiries, document request letters, and subpoenas, in violation of 18 U.S.C. § 1519. Referred to the U.S. Department of Justice.

14) The Panel made a supplemental referral to the Attorney General of New Mexico based on information produced in document productions by the University of New Mexico (UNM) and Southwestern Women's Options (SWWO), deposition testimony by *Doctor #5*, and a complaint and affidavit with supporting documents submitted by a former patient at SWWO. It details the alleged failure of SWWO and UNM to provide informed consent to women prior to using tissue from abortions for research at the university.

15) Over the course of its investigation, the Panel has uncovered documents and received testimony from confidential informants indicating that several entities, including four Planned Parenthood clinics and Novogenix, may have violated federal law, specifically Title 42 U.S.C. § 289g-2, which forbids the transfer of fetal tissue for valuable consideration. Referred to the U.S. Department of Justice.

Chapter V. Case Studies of the Fetal Tissue Industry – The Middleman Model

A. StemExpress

- StemExpress' business model was designed to obtain fresh fetal tissue from a large number of abortion clinics and provide on-demand fetal tissue to researchers around the world. StemExpress sought to sell fetal tissue "on demand" through an online procurement application.

- In 2010, StemExpress' revenue was $156,312. During 2011, that figure more than doubled to $380,000, and a year later, in 2012, StemExpress' revenue nearly tripled to $910,000. By 2013, its revenue was $2.20 million, and in 2014 the revenue had once again more than doubled to $4.50 million.

- In an attempt to expand the number of abortion clinics from which it procured fetal tissue and provide fetal tissue to a larger number of researchers, StemExpress developed and distributed a brochure aimed at abortion clinics nationwide. Further, they attempted to enter partnership agreements with the National Abortion Federation and Planned Parenthood Federation of America. If those agreements had been consummated, StemExpress would have had access to virtually every abortion clinic in the nation.

- The Panel learned that StemExpress embedded its tissue technicians at the Planned Parenthood facilities. StemExpress' embedded tissue technicians had advance knowledge of the abortions scheduled at PPFA clinics. The Panel determined that clinic personnel gave StemExpress' tissue technicians access to patients' personal medical information, in violation of federal law. The Panel determined that StemExpress' tissue technicians obtained consent to donate fetal tissue from women scheduled to undergo an abortion, procured the fetal tissue, packaged it, and shipped it directly to StemExpress' customers.

- When they obtained consent to donate fetal tissue at Planned Parenthood affiliates, the StemExpress tissue technicians used Planned Parenthood's consent form. A Planned Parenthood executive testified that the Planned Parenthood consent form was misleading and could possibly be coercive. Federal regulations bar such coercion.

- StemExpress used a consent form similar to Planned Parenthood's form at the independent abortion clinics. That form purportedly was approved by BioMed IRB, a commercial IRB that was sanctioned by the federal government for multiple violations of federal regulations. The Panel issued a subpoena to BioMed IRB; however, they produced no documents and told the Panel they had no records reflecting supervision of StemExpress' procurement activities.

- StemExpress entered contracts to procure fetal tissue from three Planned Parenthood affiliates and five independent abortion clinics. StemExpress paid those abortion clinics a total of $152,640 for fetal tissue. The Panel determined that the Planned Parenthood affiliates at which StemExpress procured fetal tissue had no legally reimbursable costs.

- The Panel sought to determine whether the doctors working at the abortion clinics changed their abortion procedures in order to increase the amount of fetal tissue StemExpress could obtain and thereby generate more revenue for the clinics. The director of one independent women's clinic from which StemExpress procured fetal tissue admitted that the abortion clinic changed its clinical practices to procure more liver. A Planned Parenthood executive acknowledged making changes to obtain tissue as well.

- The Panel uncovered evidence that StemExpress may have violated 18 U.S.C. § 1519 through StemExpress' potential destruction of documents that were the subject of congressional inquiries, document request letters, and subpoenas. The Panel made a criminal referral to the U.S. Attorney General.

- The Panel uncovered evidence that StemExpress may have violated 42 U.S.C. § 289g-2, and Cal. Health & Safety Code § 125320(a) by the receipt of valuable consideration in the form of a profit on its procurement and sale of fetal tissue. The Panel made a criminal referral to the U.S. Attorney General and the El Dorado, California District Attorney.

- The Panel uncovered evidence that StemExpress may have violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA) by accessing women's private health information. StemExpress did not have a medically valid reason to see that information. The Panel made a referral to the U.S. Department of Health and Human Services.

- The Panel found evidence that StemExpress may have violated federal regulations on informed consent and Institutional Review Boards. The Panel made a referral to the U.S. Department of Health and Human Services.

- The Panel issued a subpoena to StemExpress that required the production of its banking and accounting records. StemExpress refused to produce any of those records. Due to StemExpress' refusal to comply with repeated subpoenas, the Panel recommended that the House of Representatives hold StemExpress in contempt of Congress.

B. DaVinci Biosciences, LLC/DaVinci Biologics, LLC

- The Panel sought to determine whether DaVinci Biosciences, LLC (DaVinci), and DaVinci Biologics, LLC (DVB) may have violated 42 U.S.C. § 289g-2 and an equivalent provision of the California Health and Safety Code.

- The Panel determined that DaVinci and DVB appeared to operate a profit-driven business.

- The Orange County, California District Attorney filed a lawsuit that alleged DaVinci and DVB appeared to operate a profit-driven business and thus violated 42 U.S.C. § 289g-2.

- DaVinci and DVB charged considerably more for fetal tissue and cell lines derived from that tissue than the costs it incurs.

- The firms' business and marketing plans show that officers and directors pushed their employees to sell more and more tissue, and thus increase DaVinci and DVB's bottom line.

- The company's sole source of fetal tissue was Planned Parenthood of Orange and San Bernardino Counties (PPOSBC).

- DVB senior executives made charitable contributions to PPOSBC before the company's contract to procure fetal tissue from PPOSBC was signed.

- The DVB executives made further contributions to PPOSBC before the first procurement, and those contributions continued.

- The Panel uncovered evidence that DaVinci and DVB may have violated provisions of the California Tax Revenue and Tax Code. The Panel made a referral to the Orange County (California) District Attorney.

C. Novogenix Laboratories, LLC

- The Panel sought to determine whether Novogenix Laboratories, LLC (Novogenix) complied with all applicable federal and state laws.

- The Panel determined that Novogenix may have violated 42 U.S.C. § 289g-2, provisions of the California Health & Safety Code and the California Revenue and Tax Code, and federal regulations.

- Novogenix had a contract to procure fetal tissue from Planned Parenthood Los Angeles (PPLA). The contract provided that Novogenix would reimburse $45 per donated specimen.

- Invoices produced to the Panel by some of Novogenix's customers show that it received a total of $170,980.59 from seven research institutions between June 2011 and December 2015. The Panel cannot determine either the total number of Novogenix' customers, nor its revenue.

- Novogenix represented that it lost a total of $160,540.03 on its fetal tissue operations, but conceded that its counsel created the firm's expenses and revenue document. The Panel cannot rely on the expenses and revenue document to determine whether Novogenix actually lost money on its fetal tissue operations, because it was created by Novogenix's counsel, and Novogenix produced no primary source accounting records.

- The list of expenses included an unknown amount for attorney fees. Such fees are not included under the list of allowable reimbursements under 42 U.S.C. § 289g-2. The list of expenses also included minimal amounts for delivery to researchers. Invoices produced to the Panel by Novogenix customers show the firm charged delivery fees of up to $122.43 per shipment, raising further questions about the reliability of the attorney-created cost document.

- PPLA personnel obtained consent from patients to donate tissue from their aborted fetuses using the standard Planned Parenthood Federation of America (PPFA) consent form. That form contends that fetal tissue has been used to find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS. There is no cure for those diseases.

- Numerous witnesses, including senior PPFA officials, testified that the consent form is misleading and unethical due to its contention that fetal tissue has been used to find a cure for diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS.

- Federal regulations provide that entities cannot coerce pregnant women into the donation of fetal tissue. PPFA officials acknowledged to the Panel that the language in the PPFA consent form may be coercive. Therefore, Novogenix may have violated federal regulations.

- The California Revenue and Tax Code requires entities that collect sales tax on transactions made over the Internet within the state of California. The Panel has determined that Novogenix sold its services to customers in California; it should have collected tax on some of those transactions.

D. Advanced Bioscience Resources, Inc.

- Advanced Bioscience Resources (ABR), a non-profit corporate foundation, was started in 1989 as a resource for "biomedical, scientific, and educational purposes." It obtains fetal tissue from abortion clinics and offers it to researchers for a fee. ABR generally pays abortion clinics a flat per-tissue fee regardless of the type or amount of tissue procured. The tissue is obtained by tissue technicians embedded by ABR in abortion clinics. The technicians harvest, package, and ship the tissue to the researchers. The abortion clinic staff obtains consent from the patients for fetal tissue donations. ABR's business model is similar to that of StemExpress.

- The Panel conducted an investigation of ABR and uncovered evidence that ABR may have violated 42 U.S.C. § 289g-2 and the California Health and Safety Law. Therefore, the Panel sent criminal referrals to U.S. Attorney General Loretta Lynch and the District Attorney of Riverside County, California, urging both to investigate whether ABR violated federal and state statutes and regulations, and to take appropriate action if the investigations reveal criminal behavior.

E. Human Fetal Tissue Repository (Albert Einstein College of Medicine)

- The Panel sought to determine whether the Human Fetal Tissue Repository (HFTR) fully complied with applicable federal law and regulations. HFTR only produced a partial list to the Panel of the entities from which it received and to which it distributed fetal tissue. The Panel had insufficient evidence to determine whether HFTR complied with the applicable federal law.

- The Panel sought to determine how HFTR disposed of its stored fetal tissue after its closure. The Panel had insufficient evidence to make that determination; however, there are indications that Albert Einstein College of Medicine (Einstein) offered the tissue to the Planned Parenthood Federation of America (PPFA).

- HFTR received fetal tissue from three New York City hospitals and distributed the tissue to researchers at Einstein and fourteen other educational and research institutions.

- The Panel sought to determine HFTR's procurement procedures, including whether it had contracts with the hospitals from which it procured fetal tissue. Due to the lack of records provided by Einstein, the Panel had insufficient evidence to determine whether HFTR had contracts with those medical facilities; how much, if anything, HFTR paid for the tissue; whether the hospitals or HFTR obtained consent; how the consent was obtained; and the content of the consent form.

- The Panel sought to determine the number of women from which HFTR obtained fetal tissue, and the number of fetal tissue samples HFTR obtained. Documents produced by Einstein to the Panel show that a total of 2,701 subjects were "enrolled" in HFTR studies. The Panel had insufficient evidence to determine the number of fetal tissue samples HFTR obtained.

- The Panel sought to determine whether HFTR complied with the applicable federal regulations on research. HFTR required researchers to do the following: submit summaries of their IRB-approved protocol; provide a copy of their IRB approval letters; state what tissues they will use for their study and why they must use human tissue generally and fetal tissue in particular; and agree to use the samples in compliance with all applicable laws and regulations.

- Based solely on HFTR's limited productions, The Panel determined that it appeared HFTR complied or at least attempted to comply with the applicable HHS regulations. The Panel has insufficient evidence to make a conclusive determination whether HFTR and the research institutions to which it supplied fetal tissue fully complied with the applicable federal regulations.

Chapter VI. Case Studies of the Fetal Tissue Industry—The University/Clinic Model

- The Panel identified several research institutions across the United States, mostly state universities and virtually all recipients of federal as well as state funding, that have formed a close relationship with one or more abortion clinics.

- These institutions regularly acquire tissue from those clinics for research purposes and in some cases disseminate fetal tissue to other research institutions. Typically, the research institution requests specific human fetal organs or tissue, of a specific gestational age, from an abortion clinic, and the clinic informs the research institution when they have abortions scheduled that may produce the desired fetal body parts. Over time, the clinic thus learns which human fetal organs and tissue are useful to the research institution and often alerts the research institution to their availability without prior solicitation. Once

available, the research entities make arrangements to transfer the fetal organs and tissue from the clinic.

- In some cases, the research institutions also have relationships with tissue procurement companies. In still other cases, partnerships do not involve the transfer of fetal tissue between the clinics and universities, but they share medical school faculty and residents in common, raising additional issues about the role of government-funded institutions in driving demand for fetal tissue.

- The Panel sought to understand these and other factors relevant to its analysis of fetal tissue transactions under 42 U.S.C. § 289g-2 and to determine what role, if any, government funding plays in the transactions between abortion clinics and universities.

- The Panel examined the relationship between the University of New Mexico (UNM) and Southwestern Women's Options (SWWO), a late-term abortion clinic near the university that performs abortions through the third trimester. A tissue technician employed by UNM traveled to SWWO to procure human fetal organs or tissue an average of 39 times a year since 2010.

- The transfer of fetal tissue from SWWO to UNM was one part of an aggressive campaign under which leadership personnel at UNM medical school: (1) expanded UNM's role both in providing abortions and in training new abortion providers; (2) expanded UNM's referral for abortion services to outside clinics, including the clinic from which it obtained fetal tissue; (3) supplied residents and fellows to perform abortions for SWWO during the period that UNM was obtaining fetal tissue from that clinic; (4) expanded the faculty of UNM by providing "volunteer faculty" status to local abortionists; (5) provided staff physicians for the Planned Parenthood in Albuquerque from UNM faculty after that clinic transitioned from one owner to another; and (6) leveraged their status to organize UNM employees and students for partisan political activities.

- The close relationship between UNM and SWWO led to allegations of shoddy clinical practices, including failure to utilize a consent form for fetal tissue donation and improperly combining consent for tissue donation with consent for the underlying abortion procedure. The Panel found the consent practices appeared to violate both federal and state law governing informed consent. It also found that the transfer of fetal tissue from SWWO to UNM for research purposes is a systematic violation of New Mexico's Spradling Act, under which tissue from aborted infants cannot be anatomical gifts.

- While UNM may not have made direct payments to SWWO for the fetal tissue it received, UNM did provide the clinic a substantial value in the form of personnel offered to the clinic, in addition to conferring upon at least three staff physicians at SWWO faculty positions. Those positions gave them numerous benefits—including professional liability insurance coverage for UNM activities, access to university facilities, and

discounts. Because they did not have teaching responsibilities, these faculty members provided UNM no apparent benefit apart from the fetal tissue that came from SWWO, giving their relationship the components of an exchange of fetal tissue for valuable consideration.

- At a minimum, this arrangement violates the intent and spirit of 42 U.S.C. § 289g-2. Additionally, SWWO made a statement to the Panel that it "does not participate 'in research, study, or other work involving fetal tissue,'" which appears to be belied by both the internal and published documents that constitute evidence that the clinic and its personnel did in fact participate in fetal tissue research beyond supplying the tissue to UNM.

- The Panel's investigation into the nation's largest fetal tissue bank, the University of Washington's Birth Defects Research Laboratory (UW BDRL), and outside abortion clinics provides another example of the interdependence of clinics and public research institutions. UW BDRL received over $600,000 from the NIH for FY 2015. Over the last five years, over a dozen clinics have provided UW BDRL fetal tissue, and 40 universities or other public research institutions have been recipients of fetal tissue. UW BDRL claims that recipients of tissue are charged a flat fee of $200 regardless of the nature of the tissue researched and that the only payments it makes to clinics are to cover costs.

- The university failed to make a complete production, however. The Panel's independent research found that UW BDRL deploys doctors to outside abortion clinics and that numerous physicians on the staffs of those clinics hold faculty positions at UW BDRL. The invoices produced by UW BDRL are heavily redacted, rendering it impossible without more information to conduct a full forensic analysis under 42 U.S.C. § 289g-2 of payments made to and by UW in connection with transfers of fetal tissue.

- The Panel conducted an investigation of Planned Parenthood Gulf Coast (PPGC), a Planned Parenthood Federation of America (PPFA) affiliate that had its own research department. The Panel uncovered evidence that PPGC may have violated 42 U.S.C. § 289g-2 and Texas Penal Code § 48.02, which bar the offer to sell or transfer fetal tissue in its procurement of fetal tissue for the University of Texas Medical Branch (UTMB) and Baylor College of Medicine (BCM). The Panel also uncovered evidence that PPGC may have violated Texas Penal Code § 37.08, which makes it a crime to lie to a law enforcement officer during the course of an investigation. The Panel referred those potential violations of state law to the Texas Attorney General.

- The Panel determined that PPGC may have violated PPFA's own guidelines on programs for the donation of fetal tissue. PPFA required its affiliates that engage in fetal tissue donation to document their actual costs through an independent accountant, or accept no reimbursement. A PPGC official testified that PPGC determined its reimbursement from UTMB and BCM by back of the envelope calculations. PPGC thus had no actual knowledge of its costs.

- The Panel determined that PPGC charged UTMB $150 per executed consent, $50 if the UTMB technician did not transport the tissue, $2,000 a year in administrative and training fees, and $1,500 in staff time. Had PPGC obtained 500 patient consents for UTMB, as specified in an unexecuted contract, UTMB would have paid PPGC $75,000 for consents alone. PPGC sought to enter into a contract with BCM that contained similar payment terms. The Panel determined that BCM's Institutional Review Board (IRB) had approved the contract to procurement fetal tissue from PPGC.

- The BCM-PPGC contract negotiations terminated after a PPGC official told BCM the affiliate would not commit to the procurement or provision of fetal tissue, and stated that Texas academic institutions "cannot remain publicly silent" about their need for human fetal tissue, yet expect that "research collaboration with Planned Parenthood will remain intact." Those comments were made after the Center for Medical Progress videos were made public. A PPGC official testified that the videos were the reason for the statement.

- Nearly a year later, PPGC's attorney told Texas law enforcement officials that the reason the BCM arrangement never came to fruition was that BCM's IRB did not approve it. The Panel determined that comment was false. PPGC officials knew that BCM's IRB had approved the research project, despite the representations of PPGC's attorney to Texas law enforcement officials.

- The University of Minnesota (UM) is an example of a university that obtains fetal tissue from procurement companies—in this case, Advanced Bioscience Resources (ABR) and StemExpress—in addition to an area clinic. UM disclosed that "approximately 10 researchers at the University of Minnesota" have used such tissue "currently or in the recent past" and that UM was the recipient of well over $1 million in NIH grants for projects that used fetal tissue. UM's produced invoices from ABR show charges ranging from $275 to $2,675 that reflected ABR's varying fee schedule for different types of fetal tissue, raising questions of liability under 42 U.S.C. § 289g-2 that have been examined in the above analysis of ABR and StemExpress.

- UM's underlying fetal tissue practices potentially violate Minnesota's Anatomical Gift Act, which does not permit the donation of fetal tissue resulting from induced abortions, and another law requiring disposal of fetal remains by cremation or burial. Following disclosure of its practices, UM changed its policy to require such tissue to come from sources outside Minnesota, raising the question of whether Congress should pass legislation that would prohibit the crossing of state lines to evade state restrictions on fetal tissue use.

- Between 2010 and 2015, Colorado State University (CSU) received $3.5 million in NIH grants to support projects using fetal tissue, and it had a contractual relationship with Planned Parenthood of the Rocky Mountains (PPRM) under which CSU personnel were permitted to collect tissue from the PPRM clinic. The contract permitted reimbursement by CSU to PPRM for its "reasonable expenses incurred during the tissue process," but questions surround the actual charges, including a $1,500 charge to the University for

"Administrative Start Up" and $1,600 for consent and processing for 10 specimens. Amid the public scrutiny surrounding fetal tissue practices, CSU halted acquisition of fetal tissue from any vendors implicated in the investigation.

- Two university training programs for abortion providers, the Ryan Residency Training Program in Abortion and Contraception and the Fellowship in Family Planning, began at the University of California San Francisco (UCSF)'s Bixby Center for Global Reproductive Health. Funded by the Susan Thompson Buffett Foundation, both programs deploy and pay doctors to provide abortion and contraception services. The Fellowship in Family Planning spread to around 30 other universities and presently has 246 graduated fellows. The Ryan Program now claims 80 sites in the U.S. and Canada. UCSF is also directly involved in fetal tissue research, a component of research projects for which the university received $17.5 million from the NIH.

- Planned Parenthood of the St. Louis Region and Southwest Missouri (PPSLR), reportedly the only clinic in Missouri that provides abortions, was referenced in one of the undercover CMP videos as extensively involved in fetal tissue research, a matter that merits further inquiry. In a separate investigation, the Majority Caucus of the Missouri State Senate concluded, PPSLR "may very well have violated both state statute and Department of Health regulations in their [fetal] disposal practices."

- The Panel's investigation found that five PPSLR physicians also hold faculty positions at the Washington University School of Medicine, which offers the Ryan Fellowship as a vehicle to deploy medical residents to perform abortions at PPSLR. Further investigation is warranted into whether monetary payments or other value is exchanged among the entities' shared personnel.

- The University of Wisconsin, School of Medicine and Public Health (UW SMPH) has deployed both faculty members of its Ob/Gyn department and medical residents (by way of the Ryan Fellowship) to work at a clinic designated by Planned Parenthood of Wisconsin (PPWI). This relationship appears to have been part of a broader plan that included the procurement and transfer of fetal tissue to UW SMPH for research. The school maintains it has not obtained fetal tissue from PPWI since November 2010. The deployments continue, however. UW SMPH has more recently obtained fetal tissue for research from the Albert Einstein College of Medicine, UW, and ABR. The average charge in a UW invoice produced to the Panel, which is under $300, is lower than the lowest charge by ABR in its invoices, which range from $310 to $2,200. Given the problematical nature of ABR's practices under 42 U.S.C. § 289g-2, further investigation is warranted.

- The University of Michigan (UMich) conducts research using fetal tissue obtained from tissue procurement businesses and universities. Physicians from UMich's Health System staff a Planned Parenthood clinic in Ann Arbor, Michigan, and medical students are eligible to provide abortions there through the Ryan Fellowship. One doctor who is both medical director for Planned Parenthood and an associate professor in UMich's Ob/Gyn

department told a Center for Medical Progress journalist that the "University of Michigan IRB . . . tend to be pretty easy about stuff and actually not require informed consent." She also claimed research projects involving fetal tissue involve "grants to the agency to cover my time," raising the question of whether the grants she refers to cover more than the permissible reimbursements for costs under 42 U.S.C. § 289g-2.

Chapter VII. Case Studies of Late-Term Abortion Clinics

- The business practices and procedures of late-term clinics implicate numerous legal and ethical concerns. When human infants are born alive in late-term abortion clinics or hospitals, abortion providers are obligated to ensure that these infants are afforded all of the protections guaranteed by federal and state law. A careful investigation of late-term abortion providers is necessary to ensure that entities are complying with the federal Born-Alive Infants Protection Act, Partial-Birth Abortion Ban Act, 42 U.S.C.§ 289g, *et seq.*, federal regulations pertaining to human fetal tissue research, and state laws, including anatomical gift laws.

- The significance of this inquiry includes the issue of the taxpayers' indirect support of late-term abortion. In fact, most of the doctors west of the Mississippi who openly perform third-trimester abortions have faculty positions at either the University of New Mexico or the University of Colorado. The broad public disapproval of such practices raises the question of why institutions that receive public funds should carry the tacit imprimatur imparted by institutional affiliation.

- The Panel investigated several abortion providers and clinics across the country: [Abortion Doctor #1], [Abortion Doctor #2], [Abortion Doctor #3], the University of New Mexico, and Southwestern Women's Options. Due to the gravity of the allegations against [Abortion Doctor #3], the Panel made a criminal referral forthwith to both the United States Attorney General and the Texas Attorney General on December 7, 2016.

Chapter VIII. Case Studies of the Fetal Tissue Industry – Planned Parenthood

- Planned Parenthood executives who spoke with the Panel noted that 2016 is the 100th anniversary of the founding of Planned Parenthood. A closer look at the history of the organization, however, leaves little to celebrate. The organization was founded by eugenicists who believed in limiting the rights of people to form families and have children if they had mental or physical disabilities or were of the "wrong" race.

- Harvard studies about Planned Parenthood's business model have pointed out financial struggles the organization has faced in recent years, including smaller margins and lower revenues. Substantial evidence exists that Planned Parenthood clinics—at least 51

times—have overbilled Medicaid and improperly billed items to cover the costs of abortion services, in violation of the Hyde Amendment.

- During some of Planned Parenthood's difficult financial years, tissue procurement companies like StemExpress saw an opportunity to market their services to Planned Parenthood affiliate clinics and even the entire Federation. This move was welcomed by top Planned Parenthood executives, some of whom were remarkably candid about the revenue possibilities for clinics.

- However, the relationships that have formed between tissue procurement companies, abortion clinics, and universities are fraught with questionable practices, including the possible use of illegal, late-term abortion practices to procure fetal tissues and organs, violations of federal laws and regulations on patient consent, and systematic violations of patients' HIPAA rights.

- PPFA doctors have failed to comply with their own requirement obligating abortionists to certify in writing that they have not changed the method of the abortion to facilitate fetal tissue donation. The PPFA executive in charge of this requirement admitted to Panel staff that she has never signed a document certifying this. She additionally admitted that she regularly changed the method of abortion to facilitate intact fetal specimens.

- The Panel found no compliance with an additional PPFA requirement in a memorandum sent to affiliates by PPFA's legal department. That requirement obligated affiliates to rely on an auditor before entering into a fetal tissue donation program to ensure that fees covering allowable costs did not exceed valuable consideration. In fact, one executive told Panel staff she only uses "back of the envelope" methods to determine costs associated with the donations.

- Not only did the Panel find a shocking lack of compliance with both internal and federal regulations, but executives admitted to undercover journalists that the PPFA exercises very little control of their affiliated clinics. One even said that if clinics wanted to profit from the transfer of fetal tissue, "We can't stop them. We only have carrots and sticks."

- Accounting documents from a tissue procurement company, StemExpress, and its bank reveal substantial payments to Planned Parenthood clinics. Some expenses associated with fetal tissue donation—like storage and preservation—are allowed under federal regulations, but the Panel's analysis of these accounting records found that *both StemExpress and Planned Parenthood* claimed the same expenses.

- One of the expenses Planned Parenthood frequently claimed was "staff time" related to fetal tissue donation. However, the Panel's analysis of hundreds of Planned Parenthood job descriptions revealed that none mention the acquisition, handling or transfer of fetal tissue.

- Planned Parenthood claims it made no profit. The Panel, therefore, asked for accounting documents to prove this. Instead of turning over the records that could have proved them innocent, PPFA refused. Its lawyers wrote that "[t]he affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation, and have demonstrated conclusively that those costs exceeded the payments they received."

- "We didn't profit because we say we didn't profit" is not compliance with congressional requests for documents. Because Planned Parenthood refused to provide actual documents supporting their claim, the Panel resorted to analyzing accounting documents from middlemen companies who contracted with Planned Parenthood affiliates.

Chapter IX: Biomedical Research and Human Fetal Tissue

A. **The United States Biomedical Research Enterprise is a Success:** The Select Panel recognizes and supports the success of the United States biomedical research enterprise.

- The 2014 gross expenditure on Research and Development (R&D) in the United States exceeded $485 billion, or nearly 27% of the global R&D budget.

- The 2012 biomedical research expenditures in the United States exceeded $119 billion, with the next largest national investment being made by Japan, at just over $37 billion

- Between 2000-2013, the Unites States published approximately 40% of all papers in the area of stem cell research, with the next closest contributor (the United Kingdom) producing less than 10% of all published research in this rapidly advancing field.

B. **Scientific societies and universities have made misleading claims about fetal tissue research:** The Select Panel has received letters from 21 institutions that claim to provide evidence for the value of human fetal tissue research. The assertions of these letters fall into 8 general classes and have been uncritically repeated in the Minority report. In reality, **not a single responding institution provided substantive evidence for the value of fetal tissue research.**

- **Claim: The activities of the House Select Panel have identified scientists using fetal tissue, thereby putting them at risk:**

  False. The names, institutions and collaborators of individuals conducting human fetal research are made publicly available by the NIH.

- **Claim: Fetal tissue was used to produce vaccines for polio, measles, mumps and rubella.**

  False. These vaccines were all first produced using animal cells, not fetal tissue.

- **Claim: Fetal tissue is used for modern vaccine manufacture.**

  False. Not a single vaccine licensed in the United States is manufactured using fetal tissue.

- **Claim: We need fetal tissue to cure Zika and other brain diseases.**

  False. Fetal tissue is not widely used for Zika research and vaccines for similar viruses have not been based on human fetal tissue research.

- **Claim: Fetal tissue is important for a wide range of research.**

  False. Human fetal tissue is used in a tiny fraction of all NIH-funded research: 0.2% of the over 76 thousand NIH-funded projects.

- **Claim: Fetal tissue is important for clinical trials.**

  False. In over 100 years of unrestricted clinical research, human fetal tissue has failed to provide a single medical treatment: Human fetal tissue is used for only 0.01% of the over 230 thousand FDA-approved clinical trials—and thus far, no trials using human fetal tissue have reported positive results for patients.

- **Claim: Fetal tissue is required for scientific models such as the "humanized mouse."**

  False. Alternatives exist and are widely used.

- **Claim: Human fetal tissue is "necessary" to validate adult and induced-pluripotent stem (iPS) cells.**

  False. Almost no papers using adult and iPS cells also use fetal tissue.

C. **Response to the claim that "The Select Panel Has Thwarted Life-Saving Research:"** The Minority report asserts that human fetal tissue is important for research on many diseases. In reality, human fetal tissue research makes a vanishingly small contribution to clinical and research efforts, if it contributes at all (Table 1, below).

D. **Analysis of "successful," long-standing human fetal-tissue research:** Over the last five years (2010-14), the NIH has awarded 329 grants using human fetal tissue. **This represents 0.2% of all grants.** The Panel selected 34 "successful" fetal tissue grants that have been funded for over ten years and analyzed them in detail to objectively answer three important questions:

1. How many successful grants actually require human fetal tissue to perform the proposed experiments (*i.e.*, there are no alternatives proposed by the investigator or used in the literature)? **Answer - Eight grants of 34 (24%) actually require fetal tissue.**

2. How productive are projects involving human fetal tissue compared to non-fetal research? **Answer - Non-fetal projects produce 2.3x as many papers as fetal projects.**

3. What is the importance/impact of papers using human fetal tissue compared to non-fetal papers? **Answer - Non-fetal papers receive 2.1x more citations than fetal tissue papers.**

Conclusion: Human fetal tissue constitutes only a tiny fraction of the overall research effort. Moreover, research involving human fetal tissue is less productive and has lower importance/impact when compared to non-fetal research from the same laboratories.

E. Recommendations for improving access to ethical and appropriate scientific models

- **Recommendation 1:** Congress will appropriate funding to the NIH for a trial of expanding the organ-donation network to included preterm and stillborn infant donors, ***excluding*** tissue from elective termination of pregnancy.

- **Recommendation 2**: The NIH will undertake a study of research demand for adult human tissue and possible methods for facilitating the acquisition of this tissue for research.

- **Recommendation 3:** The NIH will establish guidelines for the use of human fetal tissue (modeled on the guidelines for animal research) and will mandate that these guidelines be applied to all grants proposing the use of human fetal tissue.

- **Recommendation 4**: The NIH will adopt a three-tiered classification system for proposals involving human fetal tissue as indicated below:

  Class 1: Fetal tissue is required for the proposed study. There are no reasonable alternatives.

  Class 2: Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist.

  Class 3: Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist.

- **Recommendation 5:** The NIH will report to Congress on the use of parent-donated tissue from natural demise of preterm children, anticipated by Recommendation 1 above, and Congress shall appropriate funds for an expansion of this program and disallow grants funded by federal dollars to utilize human fetal tissue obtained from induced abortion.

Table 1: Contribution of human fetal tissue to disease research.

Diseases Identified in the Minority Report	Grants Awarded 2015			Clinical trials			Peer Reviewed Papers		
	Fetal	Total	%	Fetal	Total	%	"Fetus"	Total	%
Alzheimer's	0	1362	0.0%	0	1956	0.0%	109	75704	0.1%
Amyotrophic lateral sclerosis	0	152	0.0%	3	360	0.8%	33	14859	0.1%
Diabetes Mellitus	6	2382	0.3%	1	14807	0.01%	1486	353110	0.4%
HIV/AIDS	74	4935	1.5%	0	7950	0.0%	372	87756	0.4%
Infant and Childhood Leukemia	0	339	0.0%	0	750	0.0%	21	1996	1.1%
Age-related Macular degeneration	5	187	2.7%	10	1371	0.7%	15	18826	0.1%
Preterm birth*	4	355	1.1%	0	3375	0.0%	503	9006	5.6%
Spinal cord injury	0	249	0.0%	8	907	0.9%	49	41461	0.1%
Vaccine research	28	2509	1.1%	0	7024	0.0%	509	280174	0.2%
Zika/Brain Disorders**	158	52338	0.3%	0	18	0.0%	6	1926	0.3%
Diseases Arising in the Fetus and/or Affecting Children	**Grants Awarded 2015**			**Current clinical trials**			**Peer Reviewed Papers**		
	Fetal	Total	%	Fetal	Total	%	"Fetus"	Total	%
Attention Deficit Disorder	0	121	0.0%	0	1277	0.0%	23	23079	0.1%
Autism	2	506	0.4%	0	741	0.0%	43	17711	0.2%
Batten Disease	0	15	0.0%	0	23	0.0%	7	1761	0.4%
Epilepsy	2	397	0.5%	0	1404	0.0%	289	141397	0.2%
Hydrocephalus	0	15	0.0%	0	135	0.0%	275	21192	1.3%
Intellectual disabilities	10	1025	1.0%	0	541	0.0%	1255	86516	1.5%
Pediatric AIDS	0	467	0.0%	0	350	0.0%	8	1586	0.5%
Pediatric cancer	0	760	0.0%	0	1642	0.0%	302	56854	0.5%
Spinal muscular atrophy	0	34	0.0%	0	157	0.0%	15	1050	1.4%
Sudden Infant Death Syndrome	1	31	3.2%	0	89	0.0%	78	7094	1.1%

Grant data is from the NIH project reporter database. Clinical data is from the clinical trials database. Publication data is from the PubMed database (queried for disease name, "fetus" and "humans" as MeSH terms.)

* The NIH does not have a spending category for preterm birth; grant data is for the broader category "Conditions affecting the embryonic and fetal periods," many of which result in preterm birth or fetal demise.

**The NIH does not have a spending category for Zika; grant data is for the broader category "Brain Disorders"

Chapter X. Recommendations

- The Panel recommends that Congress take numerous actions to provide direct protections for women and infants, including:
    - Ensuring that all donations of fetal tissue are made with informed consent;
    - Clarifying the law to ensure that abortion providers do not harm women in order to procure fetal tissue;

- Directing the Department of Health and Human Services to conduct greater oversight over misleading consent forms, IRBs, HIPAA violations, and abortion provider competence to care for infants born alive during abortion procedures;

- Ensuring that the Department of Justice allocates resources to prosecute persons or entities that profit from the sale of fetal tissue;

- Enacting a law to protect unborn infants after 20 weeks gestation;

- Directing the Department of Health and Human Services to establish protocols for abortion providers to provide emergency care to infants born alive during abortions;

- Establishing criminal penalties to enforce the Born-Alive Infants Protection Act, and;

- Establishing an office in the Criminal Division of the Department of Justice to ensure the enforcement of the Partial-Birth Abortion Ban Act, the Born-Alive Infants Protection Act, and other measures recommended in this report.

- The Panel also recommends that Congress take actions to ensure good stewardship of taxpayer funds, including:

  - Defunding Planned Parenthood and ensuring that grants no longer available to Planned Parenthood are awarded to healthcare providers that provide comprehensive preventive healthcare for their patients and that do not perform abortions (that are not covered by Medicaid under the Hyde Amendment);

  - Providing greater flexibility to states to enact laws prohibiting abortion providers form receiving Medicaid reimbursement and giving states discretion to choose subrecipients of Title X funding consistent with state policy, and;

  - Prohibiting federal funding of research involving tissue derived from induced abortions in conjunction with the establishment of a program that would fund sources of ethically obtained fetal tissue (*i.e.*, fetal tissue from *spontaneous* abortions (miscarriages) or stillbirths) for research.

- The Panel recommends that Congress take actions to improve biomedical research, including:

  - Appropriating funding to the NIH for a trial of expanding the organ-donation network to include preterm and stillborn infant donors, ***excluding*** tissue from elective termination of pregnancy.

- Directing NIH to undertake a study of research demand for adult human tissue and possible methods for facilitating the acquisition of this tissue for research.

- Directing NIH to establish guidelines for the use of human fetal tissue (modeled on the guidelines for animal research) and mandating that these guidelines be applied to all grants proposing the use of human fetal tissue.

- Directing NIH to adopt a three-tiered classification system for proposals involving human fetal tissue as indicated below:

  Class 1: Fetal tissue is required for the proposed study. There are no reasonable alternatives.

  Class 2: Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist.

  Class 3: Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist.

- Directing NIH to report to Congress on the use of parent-donated tissue from natural demise of preterm children, anticipated by Recommendation 1 above, and Congress shall appropriate funds for an expansion of this program and disallow grants funded by federal dollars to utilize human fetal tissue obtained from induced abortion.

Chapter XI: Compliance with Congressional Subpoenas

- Virtually every entity and individual from whom the Panel sought documents did not fully comply, regardless of whether the documents were required to be produced pursuant to a subpoena, or were requested via a letter.

- The chart below graphically demonstrates the level of non-compliance by entities and individuals with the Panel's document request letters and subpoenas.

Preface

The Select Investigative Panel prepared the following *Final Report* for the U.S. House of Representatives and the general public. H. Res. 461 established the Panel on October 7, 2015. The Resolution charged the Panel to investigate and report on the following:

> (1) medical procedures and business practices by entities involved in fetal tissue procurement;
> (2) any other relevant matters with respect to fetal tissue procurement;
> (3) Federal funding and support for abortion providers;
> (4) the practices of providers of second and third trimester abortions, including partial birth abortion and procedures that may lead to a child born alive as a result of an attempted abortion;
> (5) medical procedures for the care of a child born alive as a result of an attempted abortion; and
> (6) any changes in law or regulation necessary as a result of any findings made under this subsection.

The Panel's duties included completing a final, formal report to Congress no later than December 31, 2016.

Chairman Blackburn set the priorities of the Panel, directing that the interests of vulnerable women and children always inform the investigation and that the investigation encompass the nation's entire fetal tissue industry. The Chairman's direction was clear from the beginning: We must investigate alleged wrongdoing and then propose solutions to the problems we uncover. Recognizing that the transfer of fetal tissue for profit is a federal criminal offense, the Chairman focused the investigation on exacting detail, including bank and accounting records, all with a perspective that the motive for illicit profit could contaminate collateral activities in four important ways.

First, the sale of fetal tissue for profit could have a corrupting effect on the treatment of women facing an abortion decision. The Panel's work has revealed that this corruption extends to the method of obtaining consent from the patient, which is both deceptive and unlawful. Also, those entrusted with patient medical information may violate Health Insurance Portability and Accountability Act (HIPAA) privacy rights in order to enable businesses to match their customer orders for human fetal tissue with particular patients.

Second, the Panel was concerned with a history of babies being born alive and the sale of fetal tissue at some late-term abortion clinics. The Panel's investigation has revealed that whole baby cadavers of a viable age are transferred from some abortion clinics to researchers. The induction abortion procedure has increased the likelihood that infants will be born alive during abortions, even while the gestational age of viability has lowered due to medical advancements.

This intersection, coupled with a profit motive, became part of the Panel's focus throughout its tenure.

Third, the Panel found evidence that some abortion providers altered abortion procedures in a manner that substitutes patient welfare with a financial benefit for both the abortion clinic and the procurement business. Since this conduct violates federal law, a thorough investigation of the practice was critical to understanding the effectiveness of the current statute.

Fourth, the Panel discovered that profit motives taint the integrity of the nation's celebrated history of voluntary organ donation. In recent decades, much work has been done to create the highest ethical and moral standards, both in law and practice, while making progress toward healing and curing disease. Selling human fetal tissue for a profit endangers this system and threatens the future of finding cures. Thus, the Panel made recommendations that improve the tissue and organ donor system in an ethical way.

The Chairman weighed these four areas of inquiry and held the Panel's first hearing on *Bioethics and Fetal Tissue*. There have been several government-sponsored discussions on bioethics, but none directly on the transfer of fetal tissue since the 1980s. The hearing revealed substantial concern about the consent process for the donation of human fetal tissue used by abortion clinics and procurement businesses. Evidence revealed that self-interested staff, whose pay depends on the numbers of specimens donated, were assigned to obtain consent from patients. Additional evidence showed that tissue technicians and the abortion clinics violated the patient's HIPAA rights. Still other evidence revealed that some middleman companies misrepresented that the consent forms and methods of tissue harvesting comply with federal regulations regarding Institutional Review Boards (IRBs). This evidence points toward conduct focused on profit and not on patient welfare.

The Panel's next hearing, *The Pricing of Fetal Tissue*, sought the judgment of seasoned federal prosecutors to compare the federal statute prohibiting profit from fetal tissue sales with the first tranche of materials from the investigation. Two former U.S. attorneys and a senior federal litigator agreed that, based on the materials presented to them, they would open a case against a middleman company. The former prosecutors also suggested that accounting and bank records would be critical to understanding whether there was a violation of federal law. Minority witnesses agreed with this approach and urged the Panel to obtain such records.

Although the Panel has made significant progress using heavily redacted subpoenaed documents, the Minority has publicly advocated that the Panel be disbanded and has privately attempted to obstruct the Panel's fact-finding mission. At every turn, the minority has urged that the Panel's requests for information be ignored and even urged noncompliance with congressional subpoenas. At the behest of the minority, many individuals who have received congressional subpoenas have heavily redacted critical information, and some have refused to comply at all. Still others have communicated in writing that they have relied upon Minority memoranda to support their noncompliance.

A. Understanding the Final Report with Redacted Names

From the beginning of the Panel's investigation, the Chairman directed that the work focus on the transactions described in H. Res. 461, in particular the transfer of fetal tissue, the methods of abortion, and the stewardship of federal taxpayer dollars. The Legislative Branch passes and evaluates laws that govern all Americans and thus, in its Final Report, the Panel has redacted the names of individuals who engaged in those transactions and substituted descriptive nouns in their place. This allows the reader to understand the role played by an individual without disclosing the actual name of the individual.

During the Panel's investigation, several persons sought to make themselves publicly known by making personal comments in the press, including a university researcher, a late-term abortion doctor, and the CEO of a tissue procurement company. These names are also redacted from the report and replaced by descriptive nouns. The names of other individuals who perform more functionary roles, such as tissue procurement technicians or medical assistants, are also redacted and substituted with descriptive nouns. The Panel received information from confidential whistleblowers, such as former abortion clinic managers or former employees of fetal tissue procurement companies. These names are also redacted. The names of university researchers and medical students whose names appeared on the documents that were part of the transactions examined by the Panel are also redacted. Individuals abortion doctors' names are redacted. The Panel has also redacted addresses and telephone numbers where they identify particular individuals.

The Panel conducted depositions and transcribed interviews of several individuals. Those individuals' names and titles are redacted, and the transcript of their testimony before the Panel is used to explain their role.

Finally, the Panel has not redacted that names of staff of the U.S. House of Representatives, the names of lawyers who represented particular individuals or entities, the names of persons who testified before the Panel in open congressional hearings, and the non-transactional names on academic papers that the Panel relied upon to understand the role of human fetal tissue in research.

The redaction key is outlined below. The Report's exhibits, which number 3,647 pages, are also redacted. They can be found at: https://energycommerce.house.gov/news-center/letters/select-investigative-panel-final-report. Additionally, the redaction key is repeated in each individual Chapter. The Minority proposed and the Majority accepted a set of redaction placeholders for the witnesses who were deposed by the Panel and persons who volunteered to be interviewed by the Panel with a written transcript of their interview. Each attorney for the person deposed or interviewed was invited to suggest edits for the transcripts. The consensus placeholders are listed first below followed by the Report's additional redaction placeholders.

Redaction placeholders for depositions and interviews:

May 6, 2016 deponent: [Clinic A Dr. #1] Testified that she was an OBGYN abortion provider, a faculty member of University of New Mexico, and an employee of Southwestern Women's Options clinic.

May 11, 2016 deponent: [Dr. Administrator] Testified the she was an OBGYN abortion provider, a faculty Member at the University of New Mexico.

July 21, 2016 interview witnesses:

[Clinic B Staff #1] Testified that she was a medical worker at an abortion clinic in Maryland.

[Clinic B Staff #2] Testified that she was a medical worker at an abortion clinic in Maryland.

[Clinic B Staff# 3] Testified that she was a medical worker at an abortion clinic in Maryland.

[Clinic B Staff #4] Testified that she was a medical worker at an abortion clinic in Maryland.

October 6, 2016 interview witness: [PP Witness #1] Testified that she is an OBGYN abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

October 19, 2016 interview witness: [PP Witness #2] Testified that she is a manager of research projects at Planned Parenthood Gulf Coast.

November 1, 2016 interview witness: [PP Witness #3] Testified that she is a university professor, an OBGYN abortion provider, and serves on the PPFA National Medical Committee.

November 17, 2016 interview witness: [PP Witness #4] Testified that she works for the Consortium of Abortion Provider Services at PPFA, which provides technical assistance to PPFA affiliate clinics.

Additionally, each individual Chapter contains a redaction key with additional names:

Chapter I Redaction Key: No redactions

Chapter II Redaction Key:

[PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA)

who is in charge of the PPFA Manual of Medical Standard and Guidelines.

[PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council

Chapter III Redaction Key: No Redactions

Chapter IV Redaction Key: Names Redacted from Referral Letters

Chapter V Redaction Key:

StemExpress, LLC:

[PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standards and Guidelines.

[PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

[the Founder and CEO] is the founder and CEO of StemExpress, LLC (StemExpress).

[ABR's Procurement Manager] is the procurement manager at Advanced Bioscience Resources, Inc.

[FDA Consumer Safety Officer # 1] is a consumer safety officer at the U.S. Food and Drug Administration.

[FDA Consumer Safety Officer # 2] is a consumer safety officer at the U.S. Food and Drug Administration.

Novogenix Laboratories, LLC:

[PP Witness #1] Testified that she is an OBGYN abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

[PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council

[Founder and Executive Director] is the founder and executive director of Novogenix Laboratories, LLC (Novogenix).

[Supervisor Consumer Safety Officer] is a supervisor consumer safety officer at the U.S. Food and Drug Administration.

[Consumer Safety Officer] is a consumer safety officer at the U.S. Food and Drug Administration.

DaVinci Biosciences, LLC / DaVinci Biologics, LLC:

[DVB Executives] are the owners and managers of DaVinci Biosciences, LLC (DaVinci) and DaVinci Biologics, LLC (DVB).

[DVB Executive # 1] is the president of DaVinci and DVB.

[DVB Executives # 2 and 3] are founding members and officers of DaVinci and DVB.

Human Fetal Tissue Repository:

[Einstein Executive #1] is an Einstein Executive Dean

[Einstein Executive #2] is an Einstein Vice-President, Government and Community Relations

[Einstein Executive #3] is an Einstein Vice-President, External Affairs

Chapter VI Redaction Key:

[Clinic A Dr. #1] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

[Dr. Administrator] is a faculty member of the University of New Mexico.

[NM Doctor #2] is a faculty member of the University of New Mexico.

[NM Doctor #3] is a director of Southwestern Women's Options and a faculty member of the University of New Mexico.

[NM Doctor #4] is a faculty member of the University of New Mexico.

[NM Doctor #5] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

[NM Doctor #6] is an employee of Southwestern Women's Options.

[Dr. Administrator #2] is a faculty member of the University of New Mexico.

[NM Research Doctor] is a faculty member of the University of New Mexico.

[NM Patient] was a patient at Southwestern Women's Options.

[WA Clinic Director] is Executive Director and co-founder of the Cedar River Clinics.

[WA Doctor #1] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

[WA Doctor #2] is a physician who works at the Cedar River Clinics.

[WA Doctor #3] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

[WA Doctor #4] is a faculty member at the University of Washington and also works at the Cedar River Clinics.

[WA Doctor #5] previously worked at the Cedar River Clinics while a faculty member at the University of Washington.

[WA Doctor #6] is a former University of Washington resident who worked at the Cedar River Clinics and currently works at the Swedish Medical Center.

[WA Doctor #7] is a former University of Washington resident who worked at the Cedar River Clinics and currently works at Northwest Women's Healthcare.

[WA Doctor #8] is a faculty member at both the University of Washington and Northwestern University and owner and operator of All Women's Health-North.

[WA Doctor #9] is a physician who formerly worked at the Cedar River Clinics and now works at All Women's Health-North.

[WA Patient] was a patient at the Cedar River Clinics who filed a medical malpractice suit against [WA Doctor #2] for injuries alleged following an abortion performed at 25+ weeks.

[WA Doctor #10] is a former resident and current faculty member at the University of Washington who served as medical director of the Planned Parenthood of Greater Washington and North Idaho.

[WA Doctor #11] is a faculty member at the University of Washington and also works at the Planned Parenthood of Greater Washington and North Idaho.

[WA Research Doctor #1] is a faculty member at the University of Washington and the author of the university's Birth Defects Research Laboratory's NIH grant proposals.

[WA Research Doctor #2] is a research scientist at the University of Washington who has participated in fetal tissue research studies.

[WA Research Doctor #3] is a former resident at the University of Washington who has participated in fetal tissue research studies.

[WA Research Staff] is a technical operations manager at the University of Washington School of Medicine's WWAMI Institution for Simulation in Healthcare. He has participated in fetal tissue research studies.

[WA Administrator] is an administrator in the University of Washington's government relations office.

[PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

[PP Witness #2] is a manager of research projects at Planned Parenthood Gulf Coast (PPGC).

[PPFA Lawyer] is a legal official at PPFA.

[PPFA Medical Officer #1] is a PPFA official who was responsible for medical issues.

[PPFA Medical Officer #2] is a PPFA official who was responsible for medical issues.

[PPGC Abortion Doctor] is a doctor who performed abortions at PPGC.

[PPGC Staff] is a PPGC staff worker who assisted in the abortion clinic.

[UTMB Researcher # 1] is a researcher at the University of Texas Medical Branch who worked with PPGC on fetal tissue procurement.

[PPGC Abortion Services Official] is a manager of abortion services at PPGC.

[PPGC Executive] is the director of abortion services and medical director at PPGC.

[UTMB Researcher # 2] is a second researcher at the University of Texas Medical Branch who worked with PPGC on fetal tissue procurement.

[UTMB Staff] is a UTMB staff worker who administers contracts for researchers.

[BCM Researcher] is a researcher at the Baylor College of Medicine who worked with PPGC on fetal tissue procurement.

[BCM Staff] is a staff employee at the Baylor College of Medicine who worked with PPGC on fetal tissue procurement.

[BCM Contract Manager] is an employee of the Baylor College of Medicine who manages contracts.

[MO Doctor #1] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[MO Doctor #2] is Planned Parenthood of the St. Louis Region and Southwest Missouri's pathologist and the owner of Pathology Services, Inc.

[MO Doctor #3] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[MO Doctor #4] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[MO Doctor #5] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[MO Doctor #6] is or was a clinical fellow in the Ob/Gyn department of

the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

[WI Doctor #1] was an assistant professor of Ob/Gyn at the University of Wisconsin, School of Medicine and Public Health, while serving as the associate medical director of Planned Parenthood of Wisconsin.

[WI Doctor #2] is the director of the Ryan Fellowship and a member of the Ob/Gyn faculty at the University of Wisconsin, School of Medicine and Public Health, and also works at Planned Parenthood of Wisconsin.

[MI Doctor] is both an associate professor in University of Michigan's Ob/Gyn department and medical director for Planned Parenthood in Ann Arbor.

Chapter VII Redaction Key:

[Abortion Doctor #1] is an abortion provider in Nebraska and Maryland.

[Abortion Doctor #2] is an abortion provider in Colorado.

[Abortion Doctor #3] is an abortion provider in Texas.

[Dr. Administrator] is a faculty member at the University of New Mexico.

[Doctor #1] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.

[Clinic B Staff #1] is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

[Clinic B Staff #2] is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

[Clinic B Staff #3] is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

[Clinic B Staff #4] is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].

[Employee #1] is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

[Employee #2] is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

[Employee #3] is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

[Employee #4] is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].

[Patient #1] is a former patient of [Abortion Doctor #3].

Chapter VIII Redaction Key:

[PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

[PP Witness #2] is a manager of research projects at Planned Parenthood Gulf Coast.

[PP Witness #3] is a university professor, an abortion provider and serves on the PPFA National Medical Committee.

[PP Witness #4] works for the Consortium of Abortion Provider Services at PPFA which provides technical assistance to PPFA affiliate clinics.

[PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

[PPGC Abortion Services Official] is a manager of abortion services at PPGC.

[PPFA Executive] works for the Medical Standards Department at PPFA.

[PPFA Medical Officer #1] is a PPFA official who was responsible for medical issues

[PPFA Medical Officer #2] is a PPFA official who was responsible for medical issues

[PPFA Lawyer] is a legal official at PPFA.

[CRR lawyer] works for the Center for Reproductive Rights.

[ANSIRH lawyer] works for Advancing New Standards in Reproductive Health.

[NARAL executive] works for the Policy department at the National Abortion and Reproductive Rights Action League.

[StemExpress Founder and CEO] refers to the founder and CEO of StemExpress.

[Abortion Doctor] is any doctor who provides abortions.

[Researcher FT] refers to any person who is involved in fetal tissue transactions.

[Procurement Technician] refers to any person who procures fetal tissue.

Acknowledgments

The Chairman wishes to acknowledge important contributions made to the Panel's work. The General Accounting Office was very generous in providing a detailee, Pierre Kamga, a Senior Auditor who provided extraordinary guidance on all matters related to forensic accounting. Dr. David Prentice of the Charlotte Lozier Institute tutored the Members and Staff alike on the latest trends in biomedical research and helped us sharpen our thinking about the ethical issues associated with the use of abortive fetal tissue. Lastly, the Members of the Panel and their staffs performed beyond the normal, intense work-load of the House of Representatives.

I. Congress Establishes the Select Investigative Panel

A. Summary

David Daleiden, an investigative journalist, released undercover videos beginning in July 2015, recorded while posing as the head of a company interested in the fetal tissue procurement business. In numerous meetings with abortion providers and companies involved in the transfer of fetal tissue, Daleiden recorded doctors, executives, and staff-level employees discussing various aspects of the fetal tissue procurement industry. The videos and other materials that Daleiden acquired, detailed the relationship between fetal tissue procurement companies, such as Advanced Bioscience Resources, DaVinci Biologics, and StemExpress, and several abortion clinics.

The exposé followed an investigation Daleiden conducted through a not-for-profit group he founded, the Center for Medical Progress (CMP), identified on its website as "a group of citizen journalists dedicated to monitoring and reporting on medical ethics and advances."[1] CMP's first projeet, the "Human Capital" investigation, took almost three years—30 months. Working under the guise of a tissue procurement business in order to gain access to the top levels of the abortion giant Planned Parenthood, Daleiden, Susan Merritt, and other activists on the investigation recorded numerous videos documenting conversations in which Planned Parenthood executives discussed the procurement of fetal tissue (the body parts of aborted fetuses).[2]

The investigation culminated with the release of eleven videos documenting the practices of local abortion clinics and groups affiliated with the fetal tissue procurement industry. While most are familiar with the clips, Daleiden and his colleagues filmed hundreds of hours of meetings and conversations. According to the *Washington Post*, they filmed 500 hours of footage at two conferences alone.[3]

Multiple clips show abortion clinic doctors and executives admitting that their fetal tissue procurement agreements are profitable for clinics and help keep their bottom line healthy. Multiple clips also show them admitting that they sometimes changed the abortion procedure in order to obtain a more intact specimen,[4] including relying on the illegal partial-birth abortion procedure.[5] Planned Parenthood Federation of America (PPFA) also revealed that they intentionally had not set a policy about "remuneration" for fetal tissue because "the headlines

[1] Center for Medical Progress, About Us, http://www.centerformedicalprogress.org/about-us/.
[2] Center for Medical Progress, Human Capital, http://www.centerformedicalprogress.org/human-capital.
[3] Sandhya Somashekhar, *Meet the Millennial Who Infiltrated the Guarded World of Abortion Providers*, Wash. Post, Oct. 14, 2015, *available at* https://www.washingtonpost.com/national/meet-the-millennial-who-infiltrated-the-guarded-world-of-abortion-providers/2015/10/14/25aaf862-678b-11e5-9223-70cb36460919_story.html.
[4] Center for Medical Progress, Human Capital—Episode 3, http://www.centerformedicalprogress.org/blog/page/5/.
[5] Center for Medical Progress, CMP Reply to PPFA Cecile Richards Video Statement, http://www.centerformedicalprogress.org/blog/page/6/.

would be a disaster."[6] While the organization's executives told affiliates to "think, 'New York Times headline'" if this went badly,[7] at the end of the day, they thought "this is a good idea."[8]

Congress responded to the videos by holding hearings and initiating investigations. In particular, the Energy and Commerce Subcommittee on Oversight and Investigations initiated an investigation of fetal tissue transfers. The Committee on Oversight and Government Reform and the Judiciary Committee conducted hearings and also initiated investigations.

On October 7, 2015, Rep. Virginia Foxx (NC-5) managed the floor debate for H. Res. 461, a proposal for a centralized and comprehensive congressional investigation. During debate, Rep. Mimi Walters (CA-45) noted, "This resolution would create a select panel to investigate a number of claims related to Planned Parenthood's activities involving abortion and fetal tissue procurement. Like many Americans, I was horrified by the recent videos which depicted Planned Parenthood employees callously discussing the trafficking and sale of aborted babies' tissues and organs." Rep. Marsha Blackburn (TN-7) summarized:

> I want to clearly state this is about getting answers of how we treat and protect life in this country. The select panel will act to centralize the investigations that are at the Energy and Commerce Committee, Judiciary and Oversight Committees, and bring it all under one umbrella. Over the past several weeks, we have had lots of serious questions. They are troubling questions that have been asked. I think that the investigations we have had have raised a lot of those questions. It is imperative that we centralize these operations and bring it together under one umbrella.[9]

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[6] Center for Medical Progress, Press Release, *Top Planned Parenthood Exec Agrees Baby Parts Sales "A Valid Exchange," Some Clinics "Generate a Fair Amount of Income Doing This,"* http://www.centerformedicalprogress.org/2015/09/top-planned-parenthood-exec-agrees-baby-parts-sales-a-valid-exchange-some-clinics-generate-a-fair-amount-of-income-doing-this/.

[7] Center for Medical Progress, Transcript, 13, (Feb. 27, 2015), http://www.centerformedicalprogress.org/wp-content/uploads/2015/05/PPCAPSDVDfinal.pdf.

[8] Center for Medical Progress, Transcript, 12-13, 15, (Mar. 18, 2015) http://www.centerformedicalprogress.org/wp-content/uploads/2015/05/PPCAPSDVDVRfinal.pdf.

[9] 161 Cong. Rec. H6869-6872 (daily ed. Oct. 7, 2015).

Congress passed H. Res 461 by a recorded vote of 242 yeas and 184 nays.[10] Rep. Blackburn was named Chairman of the Panel. The Panel's membership is as follows:

Select Investigative Panel

Marsha Blackburn (Tennessee - 07)
Chairman

Republican Members	**Democratic Members**
Joseph Pitts (Pennsylvania - 16)	Janice Schakowsky (Illinois - 09), Ranking Member
Diane Black (Tennessee - 06)	Jerrold Nadler (New York - 10)
Larry Bucshon (Indiana - 08)	Diana DeGette (Colorado - 01)
Sean Duffy (Wisconsin - 07)	Jackie Speier (California - 14)
Andy Harris (Maryland - 01)	Suzan DelBene (Washington - 01)
Vicky Hartzler (Missouri - 04)	Bonnie Watson Coleman (New Jersey - 12)
Mia Love (Utah - 04)	

B. Center for Medical Progress Videos Raise Serious Issues

The Panel did not design its investigation to prove or disprove the credibility of tapes released by the Center for Medical Progress (CMP). The CMP engaged in a multi-year series of investigations that involved journalists posing as persons interested in growing a fetal tissue procurement business. The journalists attended conferences, befriended numerous persons in the abortion industry, and obtained documents from existing companies involved in fetal tissue procurement. During much of this undercover activity, the journalists wore unseen video recording equipment. Beginning on July 14, 2015, the CMP began to release compilations of these videos to the public. The content was alarming and troubling to many. Some said the videos were "doctored" or "highly edited." The Panel viewed the videos as a series of serious claims made by a citizen advocacy group. Thus, the Panel obtained and viewed hours of unedited footage of the CMP videos and took notice of the issues they raised. Below are the Panel's summaries of eleven videos released by CMP. The titles of each video are the CMP title for the video.

1. "Planned Parenthood Orange County Changes Abortions to Harvest Intact Fetuses for Local Company's 'Fetal Products' sales"

The Panel took notice that this video raised the issue of infants born alive during late-term abortion procedures. The video showed a discussion between the medical director of Planned Parenthood of Orange and San Bernardino Counties and undercover journalists during which the medical director admitted that her affiliate does not use digoxin. This chemical is used to kill the fetus in later 2nd-trimester abortions *and prevent a live birth*. Middleman companies

[10] *Id.* at H6879.

such as Da Vinci Biologics, LLC (who gave large donations to this Planned Parenthood affiliate), can only harvest organs from fetuses who were aborted *without* digoxin because of the poisonous effect of the chemical on fetal cells. This video prompted us to investigate late-term abortion practices in the United States and what care is provided to infants who *are* born alive during late-term abortion procedures. See Chapter VII.

2. "Planned Parenthood Ally National Abortion Federation Suggests 'Group Purchasing Program' for Fetal Parts, Payments 'A Win-Win' for Clinics"

The Panel took notice that this video raised the issue of profiting from the sale of fetal parts, a violation of 42 U.S.C. § 289g-2. In this video, an employee of the National Abortion Federation (NAF), a network of abortion clinics, suggested a "group-purchasing program" for fetal tissue and that payments from middleman companies to NAF affiliated clinics would be a "win-win." This video prompted the Panel to seek accounting records from clinics and middleman companies in order to discover if the statute preventing profit needed further examination. See Chapter V.

3. "Planned Parenthood Houston Admits Accounting Gimmicks Hide Baby Parts Sales, Invoices Charge Thousands of Dollars"

The Panel took notice that this video again raised the issue of illegal profiting from the sale of fetal parts. In this video, the director of research at Planned Parenthood Gulf Coast tells undercover journalists about accounting gimmicks which can be used to hide the sale of fetal parts. The director of research even admitted that her department **"contributes so much to the bottom line of our organization here."** Again, this prompted the Panel to seek accounting records in order to analyze the transactions that were taking place between abortion clinics, middleman companies, and buyers—usually universities. See Chapter VI.

4. "Planned Parenthood TX Abortion Apprentice Taught Partial-Birth Abortions to 'Strive For' Intact Baby Brains"

The Panel took notice that this video raised the issue of changing abortion procedures in order to harvest the most intact fetal parts. Changing the timing or method of the abortion procedure is illegal under U.S.C. § 289g. A Planned Parenthood doctor, who admitted she was trained by PPFA's senior medical advisor, described using a partial-birth abortion technique to harvest fetal organs. She told undercover journalists that she will sometimes use ultrasound guidance to convert a 2nd-trimester fetus to a feet-first breech presentation: "That's what [PP Doctor] was telling us, was it really makes a difference for tissue collection at PPLA." This prompted the Panel to interview and depose abortion providers who it thought might be involved with fetal tissue collection, as well as subpoena and examine clinic manuals and procedure guides that relate to fetal tissue procurement methods. See Chapter VIII.

5. "Top Planned Parenthood Exec Agrees Baby Parts Sales 'A Valid Exchange,' Some Clinics 'Generate a Fair Amount of Income Doing This'"

The Panel took notice that this video again raised the issue of illegal profiting from the donation of fetal parts, as well as the apparent endorsement of these practices by senior Planned

Parenthood executives. In this video, the National Director for the Consortium of Abortion Providers (a key committee within PPFA that shapes abortion policy) referred to fetal tissue payments as "donation remuneration." She also admitted that she had been "talking to the executive director of the National Abortion Federation, we're trying to figure this out as an industry, about how we're going to manage remuneration, because the headlines would be a disaster." This prompted the Panel to interview top Planned Parenthood executives in order to ascertain their understanding of federal and state regulations, as well as their protocols of compliance surrounding the transfer of fetal tissue, in addition to seeking accounting information. See Chapter VIII.

6. "Planned Parenthood Baby Parts Vendor Advanced Bioscience Resources Pays Off Clinics, Intact Fetuses 'Just Fell Out'"

The Panel took notice that this video raised the issue of illegal profiting and born-alive infants. The former director of Planned Parenthood of the Pacific Southwest seems to affirm undercover journalists' offer to pay for tissue. When they say, "We return a portion of our fees to the clinics," the director responds eagerly, "**Right, get a toe in and make it, make a pro– alright.**" The video also featured the Procurement Manager at ABR, who described situations where enough dilation occurred to procure an intact fetus. "**I literally have had women come in and they'll go in the O.R. and they're back out in 3 minutes, and I'm going, 'What's going on?' Oh yeah, the fetus was already in the vaginal canal whenever we put her in the stirrups, it just fell out.**" This prompted the Panel to investigate late-term abortion practices. See Chapters V and VII.

7. "Planned Parenthood Baby Parts Buyer StemExpress Wants 'Another 50 Livers/Weeks,' Financial Benefits for Abortion Clinics"

The Panel took notice that this video raised the issue of a callous tone and unethical behavior towards scientific research, late-term abortions, and fetal tissue procurement. CEO of StemExpress told undercover journalists about shipping aborted fetal cadavers to researchers after abortions and the reactions of scientists:

> ...Tell the lab it's coming! So they don't open the box and go, "Oh God!" [laughter] So yeah, so many of the academic labs cannot fly like that, they're not capable...It's almost like they don't want to know where it comes from. I can see that. Where they're like, "We need limbs, **but no hands and feet need to be attached**." And you're like, ? Or they want long bones, and they want you to take it all off, like, make it so that we don't know what it is...But we know what it is. I mean, [laughter], but their lab... **And their lab techs freak out, and have meltdowns.**

The CEO was also asked what would "make her lab happy," to which she responded, "**Another 50 livers a week...We're working with almost like triple digit number clinics,**" she explains, "**and we still need more.**" She later noted, "**Planned Parenthood has volume, because they are a volume institution.**" She also suggested that abortion clinics profit from fetal tissue

donation. This prompted the Panel to examine the attitude towards fetal tissue donation. See Chapter V.

8. "Intact Fetuses 'Just a Matter of Line Items' for Planned Parenthood TX Mega-Center"

The Panel took notice that this video raised the issue of Planned Parenthood affiliate clinics breaking their own protocols in order to contract and conduct business with fetal tissue procurement companies. The director of research at Planned Parenthood Gulf Coast told undercover journalists: "**Where we probably have an edge over other organizations, our organization has been doing research for many many years.**" When researchers need a specific part from the aborted fetus, she says, "**We bake that into our contract, and our protocol, that we follow this, so we deviate from our standard in order to do that.**" She also admitted that some doctors change their procedure in order to procure the most intact specimen. This prompted the Panel to study the regulations around fetal tissue procurement and examine how closely those regulations are being followed. She also said of budgeting for fetal tissue, "**It's all just a matter of line items.**" This prompted the Panel to see how well Planned Parenthood executives understand the federal regulations surrounding fetal tissue. See Chapter VI.

9. "Planned Parenthood VP Says Fetuses May Come Out Intact, Agrees Payments Specific to the Specimen"

The Panel took notice that this video again raised the issue of born-alive infants because Planned Parenthood employees discussed delivering intact fetuses after an abortion. At Planned Parenthood of the Rocky Mountains, [Abortion Doctor] said, "**Sometimes, if we get, if someone delivers before we get to see them for a procedure, then we are intact.**" Again, because this affiliate does not use the feticide digoxin in 2nd trimester procedures, there is the potential that "intact deliveries" are born alive. This prompted the Panel to investigate late-term abortion procedures. She also said she would need to train doctors to change the abortion procedure in order to harvest the most intact brains if PPRM were to partner with the fake tissue procurement company. And finally, [Abortion Doctor] said, "**I think a per-item thing works a little better, just because we can see how much we can get out of it.**" This prompted the Panel to see if clinics were profiting from the transfer of fetal tissue, a violation of federal law. See Chapters VII and VIII.

10. "Second Planned Parenthood Senior Executive Haggles Over Baby Parts Prices, Changes Abortion Methods"

The Panel took notice that this video again raised the issue of illegal profit. Another Planned Parenthood executive, the President of the Medical Directors' Council, bargained with undercover journalists over the price of fetal tissue. **"You know, in negotiations whoever throws out the figure first is at a loss, right?"** She explains, "**I just don't want to lowball.**" If Planned Parenthood loses money as they say they do by participating in fetal tissue programs, then "lowballing" wouldn't be a factor in contract negotiations. And even though she insists, "We're not in it for the money," she says, "**But it has to be big enough that it's worthwhile for me.**" This again prompted the Panel to seek accounting records and other records relating to Planned Parenthood's fetal tissue programs. See Chapter VIII.

11. "Planned Parenthood Uses Partial-Birth Abortions to Sell Baby Parts"

The Panel took notice that this video raised multiple issues: illegal profiting, changing the abortion procedure in order to procure a better specimen, the possible use of partial birth abortion, and the disregard of federal regulations. In the video, the Senior Medical Advisor to Planned Parenthood, discusses how she changes the abortion procedure to procure an intact calvarium (upper skull): **"We've been very good at getting heart, lung, liver, because we know that, so I'm not gonna crush that part, I'm gonna basically crush below, I'm gonna crush above, and I'm gonna see if I can get it all intact." "But I will tell you that behind closed doors these conversations are happening with the affiliates.** When asked about Planned Parenthood's position on fetal tissue procurement, she tells the journalists, "**behind closed doors these conversations are happening with the affiliates.**" She stressed that Planned Parenthood is treading very carefully around the issue in order to "avoid headlines," a frequently repeated phrase in conversations among executives. This prompted the Panel to investigate late-term abortion practices to see if they were being modified to procure tissue, as well as to interview multiple Planned Parenthood executives. See Chapters VII and VIII.

C. The Panel Forms an Investigative Plan

On March 10, 1993, the House debated two competing amendments to H.R. 4, the National Institutes of Health Revitalization Act of 1993. The amendments, one offered by Rep. Bliley and one by Rep. Waxman, focused on safeguards governing the donation of fetal tissue for transplantation and for research. The House passed the Waxman Amendment to H.R. 4, the National Institutes of Health Revitalization Act of 1993. That Amendment includes the provisions codified as 42 U.S.C. §§ 289g-2(a) and (e)(3):

> **42 U.S.C. § 289g-2(a) states "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."**
>
> **42 U.S.C. § 289g-2(e)(3) "The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."**

During floor debate it was repeated over and over by supporters of the Waxman Amendment that "fetal tissue may not be sold."[11] Rep. Morella expressed her support for the legislation because "fetal tissue could not be sold."[12] Rep. Waxman himself said:

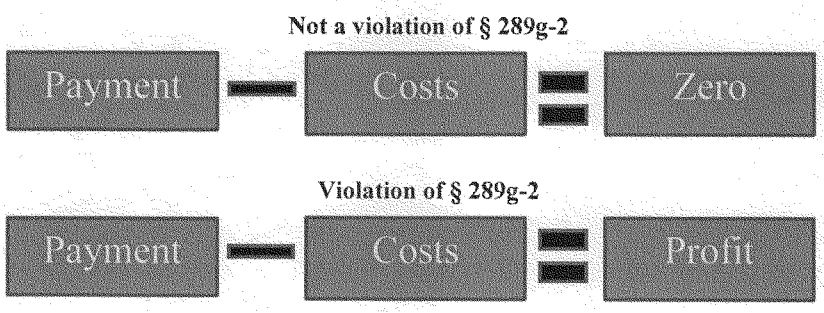
> This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any purpose, just not for the purpose of

[11] 139 Cong. Rec. H1099 (1993) (statement of Rep. John Edward Porter in support of the Waxman Amendment).
[12] *Id.* (statement of Rep. Connie Morella in support of H.R. 4 and the Waxman Amendment).

> research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.[13]

The floor debate corroborates the Committee Report language. The Report from the Committee on Energy and Commerce stated, "Section 498B prohibits the purchase of human fetal tissue as well as the solicitation or acceptance of directed fetal tissue donations."[14] The Committee prohibition on the sale of fetal tissue is described as making the transfer of fetal tissue parallel with donation of other organs under the Organ Procurement and Transplantation Act.[15] The Committee Report adds, however, "Indeed the Committee has dealt with fetal tissue more restrictively . . . ."[16] The Committee intent is to disallow payment for procurement of any organs.

The intent of the statute is best understood through a simple contrast between two modes of transferring fetal tissue from one entity to another. With the first, an abortion clinic or middleman Procurement Business transfers tissue to a researcher, and the researcher may reimburse the abortion clinic or Procurement Business for its reasonable costs incurred by the transportation, processing, preservation, and quality control of the tissue. With the second, the payment from the researcher exceeds those reasonable costs, enabling the abortion clinic or Procurement Business to make a profit, and thus violates the statute.



The congressional intent of the Waxman Amendment served as a guide for the Panel's investigative plan. The core question became the following: If fetal tissue is transferred from one entity to another, does the transfer violate the intent of § 289g-2? To answer this question, the panel identified four business. These are:

(1) *The Middleman Model.* This model comprises a middleman and tissue procurer who obtains tissue directly from a source such as an abortion clinic or hospital and then transfers the tissue to a customer, usually a university researcher.

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[13] *Id.* (statement of Rep. Waxman).
[14] H.R. Rep. No. 103-28 at 76 (1993).
[15] Pub. L. No. 98-507, 98 Stat. 2339 (1984).
[16] H.R. Rep. No. 103-28 at 76 (1993).

(2) *The University/Clinic Model.* This model comprises a particular university that has formed a close relationship with a nearby abortion clinic and regularly acquires tissue from that clinic for research purposes.

(3) *The Biotech Company/Clinic Model.* This model comprises a close relationship between a particular biotech company and one or more nearby clinics.

(4) *The Late-Term Clinic Model.* This model is of particular concern due to the intersection of late-term abortions, the potential for live births during the abortion procedure, and the transfer of tissues or whole cadavers from that clinic to research entities.

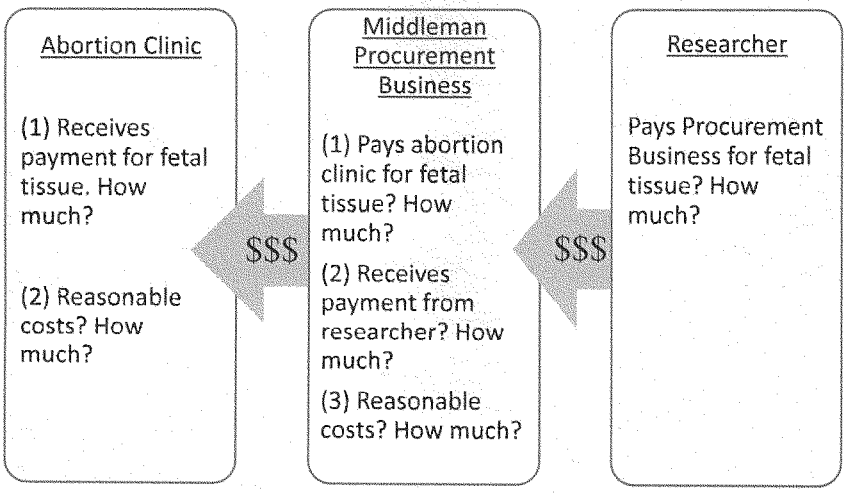
The Panel sought information from the following entities. Scientists from Harvard University and Pfizer provided bipartisan, off-the-record informational briefings for staff which gave a candid view into their view of fetal tissue research.

1. Advanced Bioscience Resources, Inc.
2. Albert Einstein College of Medicine
3. American Academy of Pediatrics
4. American Association for the Advancement of Science
5. American College of Obstetricians and Gynecologists
6. American Type Culture Collection
7. Anatomic Gift Foundation
8. Association of American Medical Colleges
9. Baylor
10. Bioarray Therapeutics
11. Buffalo Biosciences
12. Butler Medical Transport
13. Camelback Family Planning
14. Capital Biosciences
15. CEO StemExpress
16. Cedar River Clinics
17. Colorado State University
18. [Dr. Administrator] University of New Mexico
19. [MO Doctor #2]
20. [NM Research Doctor]
21. Dv Biologics
22. Family Planning Specialists Medical Group
23. Five Star
24. Germantown Reproductive Health Services
25. Harvard University – Provided Briefing
26. HHS
27. Holy Cross Germantown Hospital
28. InVivo Therapeutics
29. [Abortion Doctor #1] (Document Production and Deposition)
30. Life Technologies
31. Maryland Board of Physicians
32. Montgomery County Department of Fire and Rescue Services
33. Montgomery County Emergency Communications Center
34. Montgomery County Police Department
35. NAF
36. Neuralstem
37. NIH
38. Northland Family Planning
39. Novartis
40. Novogenix Labs
41. Oregon Health Sciences
42. Pfizer – Provided Briefing
43. Presidential Women's Center
44. Q Therapeutics
45. Saneron CCel Therapeutics, Inc.
46. Former Accountant StemExpress

Bancorp – StemExpress' bank

47. SciKon
48. Scinto Group, LLP – StemExpress' accountant
49. Shady Grove Adventist Hospital
50. Southwestern Women's Options
51. Stem Cell Innovations
52. StemCells, Inc.
53. StemExpress
54. The Center for Medical Progress (CMP)
55. CEO and Chairman, AOL, Inc.
56. County of Orange, State of California
57. University of Colorado
58. University of Michigan
59. University of Minnesota
60. University of Texas
61. University of Wisconsin
62. University of California, San Diego
63. University of New Mexico
64. University of Washington Birth Defects Research Laboratory
65. U.S. Department of Justice
66. University of Southern California – Keck
67. Women's Health Specialists
68. Yale University

The Panel started its inquiry into the middleman or tissue broker model, the primary business model for the transfer of human fetal tissue. The statute raises several fundamental questions about this model as displayed by the graphic below.



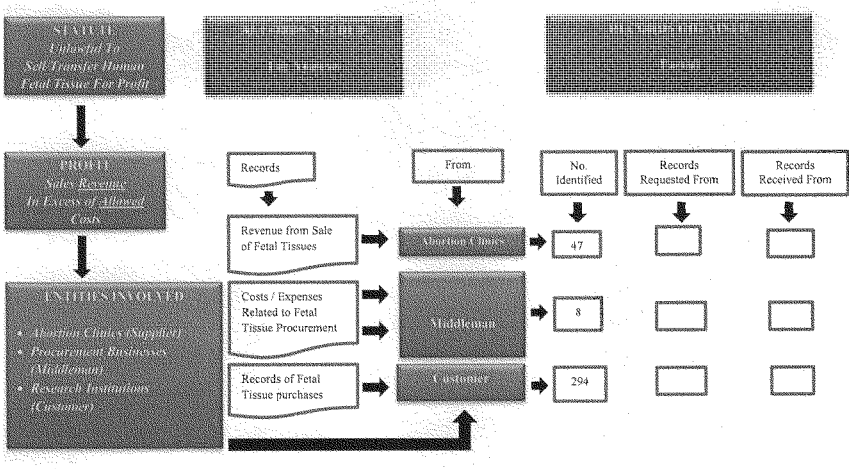
D. Middleman Investigative Work Plan Overview

The Panel relied upon the advice of a forensic accountant to formulate an investigative work plan. The statute (Section 289g-2) states that the term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. The Panel relied on generally accepted accounting standards, which defined payments made (including costs incurred) that are reflected as expenses, and payments received that are reflected as revenue (or income, from selling a product or service). Together these formed the Panel's basis for seeking accounting records of the business transactions of the fetal tissue procurement middleman companies, the abortion clinics from which they harvested fetal tissue, and the customers that purchased fetal tissue. The Panel sought to understand the transactional data, reflected on income statements and balance sheets. Also, the Panel relied upon the requirement that nonprofit entities comply with Internal Revenue Service (IRS) requirements to keep records that clearly show their income and expenses in order to substantiate deductions and claims made on their tax returns.

For the Panel to complete its review and determine the extent to which an entity did not receive valuable consideration allowed by the statute (or violated the statute), a thorough examination of the accounting records is necessary. Payments made and/or received as described in the preceding paragraph are embedded in accounting records. Each time a company makes a financial transaction, a paper trail is generated, also known as a source document. These source documents include but are not limited to cancelled checks, original invoices, sales receipts, bank transaction records, leases & contracts, purchase orders, etc. These source documents form the basis to substantiate any assertions made by an entity, through its financial or accounting records (including a trial balance report, an income statement or records of profit and loss, a statement of cash flow and a balance sheet). The Panel sought such documentation, but many entities refused to comply, even with lawful congressional subpoenas.

The Panel's document requests and subpoenas reflected these accounting standards: In order to do a forensic examination of accounting and financial records, those financial records have to be completely presented and handed over to the auditors, examiners, or investigators. The responsibility to substantiate entries, deductions, claims, or other assertions made on the financial records (arising through review of the records) is on the entity providing the documentation. Without sufficient and appropriate substantiation, accounting principles view such records as inaccurate, incomplete, invalid, or unreliable.

Thus, the Panel was able to reach partial conclusions about the sufficiency of the statute that governs fetal tissue transfers. The Panel has made criminal referrals to law enforcement agencies that have additional investigative tools. The graphic chart below illustrates the Panel's work plan for an examination of accounting documentation.


STATUTE
Unlawful To
Sell Transfer Human
Fetal Tissue For Profit
PROFIT
Sales Revenue
In Excess of Allowed
Costs
ENTITIES INVOLVED
Abortion Clinics (Supplier)
Procurement Businesses
(Middleman)
Research Institutions
(Customer)
Records
From
No. Identified
Records Requested From
Records Received From
Revenue from Sale of Fetal Tissues
Abortion Clinics
47
Costs / Expenses Related to Fetal Tissue Procurement
Middleman
8
Records of Fetal Tissue purchases
Customer
294

II. Applicable Laws, Regulations, and Commissions

Chapter II Redaction Key:

1. [PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standards and Guidelines.

2. [PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

Given the breadth of the Select Investigative Panel's authorization, the Panel examined numerous federal and state laws which can be grouped into four broad categories, with some overlap: (1) laws protecting human research subjects and patient privacy; (2) laws regulating anatomical gifts for transplantation, therapy, research, and education; (3) laws protecting late-term and born-alive infants; and (4) laws pertaining to public funding for fetal tissue research and abortion providers.

Laws protecting human research subjects and privacy are rooted in the principles set forth in the Belmont Report. Research subjects must be respected as autonomous persons, researchers must adhere to the Hippocratic ideal, and the benefits of research must outweigh the risks to human research subjects. The Panel heavily examined the legal and ethical importance of informed consent.

Laws regulating anatomical gifts are also heavily centered on the need for informed consent. Additionally, federal and many state laws explicitly prohibit the sale of human body parts. Laws protecting late-term unborn infants and infants born alive during abortion procedures recognize that the "right to an abortion" does not equal the right to a dead child. Federal laws prohibit a specific abortion procedure that occurs seconds before live birth and explicitly provide that infants born alive enjoy all of the constitutional rights available to other Americans.

Finally, laws pertaining to public funding for fetal tissue research and abortion providers need reforming. In particular, while federal law contains numerous restrictions on public funding for abortion, abortion providers receive millions of federal dollars ostensibly for other purposes. Government investigations and whistleblower testimonies have revealed that abortion providers often fail to separate public funding from abortion-related costs.

A. Laws Protecting Human Research Subjects and Patient Privacy

1. The Belmont Report

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created on July 12, 1974, with the passage of the National Research Act.[17] The Act was largely a response to the reprehensible Tuskegee Syphilis study, in which

[17] P.L. 93-348.

African-American men were asked to participate without informed consent. These men were not given adequate treatment for their disease, even after penicillin became the accepted drug for treating syphilis in 1947. In 1972, an advisory panel concluded that the Tuskegee Study was "ethically unjustified."[18]

The National Commission was tasked with identifying "the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects" and developing "guidelines which should be followed to assure that such research is conducted in accordance with those principles."[19] The Commission's work culminated in the issuance of the Belmont Report. This seminal report set forth three principles of biomedical research:

> (1) **Respect for persons**, with consideration given to individuals' autonomy. This principle underlies the requirement of obtaining a patient's informed consent.
>
> (2) **Beneficence**, reflecting the Hippocratic ideal of doing no harm.
>
> (3) **Justice**, with potential benefits of research balanced against the risks to subjects (*i.e.*, people).

The Belmont Report's relevance to the Panel's investigation was clear during the Panel's hearing on *Bioethics and Fetal Tissue*. Rep. Vicky Hartzler (MO-4) addressed an important statement in the Belmont Report regarding informed consent—that "inducements [to consent] that would ordinarily be acceptable may become undue influences if the [research] subject is especially vulnerable."[20] She asked an ethics expert if a form known to be widely used by abortion clinics to obtain a mother's consent to donate fetal tissue complied with "HHS's mandate against inducement."[21] The form stated that "[r]esearch using the blood from pregnant women and tissue that has been aborted has been used to treat **and find a cure** for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[22]

The witness agreed that this was an important question because the "idea of the promise of cures" found in the form was a "very powerful motivator."[23] The witness also

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[18] *See* The Tuskegee Timeline, CDC, http://www.cdc.gov/tuskegee/timeline.htm.
[19] *See* The Belmont Report, Office of the Sec., Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Summary (1979), http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.
[20] The Belmont Report, Office of the Sec., Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.
[21] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. 77 (unedited transcript) (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.
[22] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. Majority exhibit A-3 (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD030.pdf (emphasis added).
[23] *Id.*

indicated that the "consent" form was deficient in other ways: "The concern I have is that the standards that we have typically for fetal tissue donation are just absent here. And so in addition to the voluntariness, there is just the thoroughness of the consent [that] seems to be missing in this form."[24]

A researcher invited by the Minority during the hearing agreed, stating that the form would not have "made it past" his IRB.[25] The testimony provided by witnesses invited by both the Majority and Minority raised concerns that the principles embodied in the Belmont Report, and later incorporated into federal regulations, are not being followed by abortion providers seeking consent for the donation of human fetal tissue.

During the hearing, Rep. Mia Love (UT-4) expressed deep concern with the issue of consent and minors. She stated: "So, imagine [a] 14-year-old going into a clinic to undergo a very invasive procedure without someone there that she trusts to walk her through, to make sure that she is not being taken advantage of, to make sure that she is making the right decision."[26] She asked, "How can anyone be sure that that minor, under difficult circumstances, fully understand[s] the long-term repercussions behind [her] decision when the current law wouldn't even allow that minor to get behind the wheel of a vehicle?"[27] Dr. G. Kevin Donovan, a witness, agreed that this presented a troubling problem.[28]

2. The Common Rule and IRB Regulations

In response to the Belmont Report, HHS and the FDA significantly revised their human subjects regulations in 1981.[29] The Common Rule[30] applies to research projects that receive funding from any one of 19 federal agencies. It requires three steps to be fulfilled before the research can take place: 1) the human subject must give informed consent; 2) an Institutional Review Board (IRB) must review the proposed research project; and 3) the institution conducting the research must file an assurance of compliance with the federal agency that is providing the funding. For fetal tissue, if the researchers would like access to the woman's medical information, then the HIPAA Privacy Rule applies, and she must give consent for that information to be shared.

The rule lists several criteria for IRB approval, including the requirement that researchers obtain the informed consent from their research subjects. There are eight basic elements of informed consent under the Common Rule that "shall be provided to each subject."[31] The HHS regulations also require an IRB to "prepare and maintain adequate documentation" of its activities.[32]

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[24] *Id.* (testimony of Paige Cunningham).
[25] *Id.* (testimony of Lawrence Goldstein).
[26] *Id.*
[27] *Id.*
[28] *Id.* (testimony of G. Kevin Donovan).
[29] 45 C.F.R. § 46; 21 C.F.R. § 50; *See* Erin D. Williams, Cong. Research Serv., RL32909, Federal Protection for Human Research Subjects: An Analysis of the Common Rule and its Interactions with FDA Regulations and the HIPAA Privacy Rule 78 (2005).
[30] 45 C.F.R. § 46.
[31] 45 C.F.R. § 116.
[32] 45 C.F.R. § 46.115(a).

The Panel's investigation revealed evidence that the IRB process used by some fetal tissue procurement companies is often grossly insufficient. For instance, on March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of federal regulations, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval.[33] BioMed IRB's executive director informed the Panel on April 4, 2016, that, in regards to those records, "there are none."[34] This is an apparent direct violation of federal regulations.

3. Presidential Commissions

Since 1974, "public national bodies" have had a role in the national debate surrounding bioethics. These groups have grappled with topics ranging from human subject research to end-of-life care to stem cell research. Their studies have most frequently been conveyed through reports, policy proposals, and hearings. Furthermore, fetal tissue research has been a topic of their conversations since the first commission.

In addition to the Belmont Report, the first group published a report called *Research on the Fetus* (1975), in which they said their primary concern was "research on the fetus . . . before, during and after induced abortion." While they recommended "that use of the dead fetus, fetal tissue and fetal material for research purposes be permitted," several members of the commission (both for and against abortion) argued that research on fetuses past viability was unethical. They also recommended that the method of abortion should not be changed for research purposes and that no financial inducements "be offered to procure an abortion for research purposes."[35]

President Reagan's **Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research** (1978-1983) added an important voice to the discussion of euthanasia with their report *Defining Death*,[36] which served as the basis for the Uniform Determination of Death Act subsequently enacted by most states. Their report *Screening and Counseling for Genetic Conditions* (1983)[37] discussed in part the ethics of having abortions based on the knowledge of the sex or various disabilities of the fetus.

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[33] Subpoena from Select Investigative Panel to Biomedical Research Institute of America (Mar. 29, 2016).
[34] Email from Executive Director, Biomedical Research Institute of America, to Select Investigative Panel staff (Apr. 4, 2016).
[35] *See* Research on the Fetus, U.S. Dept. of Health, Ed., & Welfare, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1975), https://videocast.nih.gov/pdf/ohrp_research_on_fetus.pdf.
[36] *See* Defining Death: Medical, Legal, and Ethical Issues in the Determination of Death, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1981), https://repository.library.georgetown.edu/bitstream/handle/10822/559345/defining_death.pdf?sequence=1&isAllowed=y.
[37] *See* Screening and Counseling for Genetic Conditions: The Ethical, Social and Legal Implications of Genetic Screening, Counseling, and Education Programs, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1983), https://repository.library.georgetown.edu/bitstream/handle/10822/559349/geneticscreening.pdf?sequence=1&isAllowed=y.

The **Advisory Committee on Human Radiation Experiments** (1994-1995), created by President Clinton, investigated human radiation experiments conducted from 1944-1974, while his second commission, the **National Bioethics Advisory Commission**, set out in part to "familiarize professionals engaged in nonfederally-funded research with the ethical considerations associated with conducting research involving human subjects."[38]

President George W. Bush's **Presidential Council on Bioethics** (PCBE) is perhaps most renowned for the academic seriousness with which it approached bioethics. Guided by the belief that respect for human life and advancing biotechnology were compatible, President Bush appointed a diverse group of scientists and ethicists to the Council to advise him, particularly in regard to embryonic stem cell research. President Bush was especially concerned that research using embryonic stem cells, which he believed ended human lives, was unethical. He relied on policy recommendations from the PCBE to promote bills prohibiting biomedical practices he found morally objectionable. For example, the Fetus Farming Prohibition Act of 2006 was a response to the PCBE's report *Reproduction and Responsibility,* whose policy recommendations attempted to limit questionable practices, particularly by instituting (at least temporarily) moratoriums on those affecting reproduction.[39] The Fetus Farming bill made it a federal crime to be involved in interstate commerce to acquire "human fetal tissue knowing that a human pregnancy was deliberately initiated" to provide the tissue.[40]

The Panel's research found that—even with the material produced by these commissions—answers to many questions were out of date or nonexistent. Of particular concern are current practices in tissue and organ donation; research ethics and the revolution in biotechnology; the ability of the regulatory agencies to address misconduct; and the role of law enforcement. Many of the Panel's questions directed to the Federal Drug Administration and the National Institutes of Health could not be answered at all. The U.S. Department of Justice wrote to the Panel that it had never conducted training on the criminal statute that makes profiting from human fetal tissue sales a felony. The same letter could provide no example of attorney training or convictions under the statute.

4. HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule (Privacy Rule) protects all individually identifiable health information held or transmitted by a covered entity or its business associate and calls this information protected health information (PHI).[41] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security number), and includes demographic data relating to an individual's past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.[42]

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[38] *See* Exec. Order No. 12975, "Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission" (1995), https://bioethicsarchive.georgetown.edu/nbac/about/eo12975.htm.
[39] *See* Reproduction and Responsibility: The Regulation of New Biotechnologies, The President's Council on Bioethics (2004), https://bioethicsarchive.georgetown.edu/pcbe/reports/reproductionandresponsibility/.
[40] Pub. L. No. 109-242; 42 U.S.C. § 289g-2.
[41] 45 C.F.R. § 160.103.
[42] *Id.*

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires[43] or as the individual or their representative authorizes in writing. HHS may impose civil penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses and any person who knowingly obtains PHI in violation of the Privacy Rule can face criminal fines or imprisonment.[44]

The Panel's investigation uncovered a series of business contracts between StemExpress, a tissue procurement business (TPB), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

The Panel's investigation indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) (the abortion clinics) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. These violations occurred when the abortion clinics disclosed patients' individually identifiable health information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

From about 2010 to 2015, the abortion clinics (covered entities under HIPAA) permitted employees of StemExpress (a non-covered entity) to enter their clinics and procure human fetal tissue from aborted infants, obtain PHI about their patients, interact with patients, and seek and obtain patient consent for tissue donation.[45] StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefited StemExpress and the clinics.[46]

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (a) the disclosures of patients' PHI made by the abortion clinics and received by StemExpress were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (b) the consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (c) the disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (d) StemExpress is not a "business associate" of the abortion clinics under HIPAA.

The abortion clinics could have directly consented their patients for tissue donation and entered an agreement with StemExpress to provide a limited data set regarding the patients they were seeing on a particular day.[47] Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

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[43] 45 C.F.R. § 164.502(a).
[44] Pub. L. No. 104-191; 42 U.S.C. §§ 1320d-5-1320d-6.
[45] *See* Clinic Procedures & Policies, produced by StemExpress, Exhibit 2.1.
[46] *See* Standard Operating Procedure, produced by StemExpress, Exhibit 2.2.
[47] *See* 45 C.F.R. § 164.514(e).

These disclosures made by the abortion clinics to StemExpress were intentional and purposeful.[48] StemExpress employees were handed a patient's medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. Laws Regulating Anatomical Gifts for Transplantation, Therapy, Research, and Education

1. National Organ Transplant Act

The National Organ Transplant Act (NOTA)[49] was enacted in 1984, providing for the establishment of the Task Force on Organ Transplantation. The Act also authorized the Secretary of Health and Human Services to make grants for organ procurement organizations, created the Organ Procurement and Transplantation Network (OPTN), created the Scientific Registry of Transplant Recipients, and created an administrative unit within HHS to administer these activities. Importantly, NOTA included a criminal prohibition against the exchange of organs for transplantation for valuable consideration.[50]

NOTA provides that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. . . . Any person who violates [] this section shall be fined not more than $50,000 or imprisoned not more than five years, or both." The term "human organ" is defined to include fetal organs and subparts of organs.[51]

2. Uniform Anatomical Gift Act

The Uniform Anatomical Gift Act (UAGA), a model statute first available in 1968 and most recently amended in 2009, was written to facilitate organ donation for transplantation, therapy, research, and education by ensuring that state laws are consistent across the country.[52] The UAGA, adopted in every state in some form, includes stillborn babies and fetuses in the definition of "decedent" for purposes of obtaining consent from a relative before the deceased infant's body is donated for experimentation or transplantation. In the UAGA's official notes, the drafters explain that the inclusion of stillborn babies and fetuses ensures that they "receive the statutory protections conferred by this [act]; namely that their bodies or parts cannot be used for transplantation, therapy, research, or education without the *same appropriate consents* afforded other prospective donors."[53]

However, the notes also mention that states may choose to treat aborted fetuses

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[48] *See* 45 C.F.R. § 164.502(a)(1)(iii).
[49] 98 P.L. 507; 98 Stat. 2339.
[50] *See* U.S. Dept. of Health & Human Services, Selected Statutory and Regulatory History of Organ Transplantation, http://organdonor.gov/about-dot/laws/history.html.
[51] 42 U.S.C. § 274e.
[52] *See* Revised Uniform Anatomical Gift Act (2006) (Last Revised or Amended in 2009), drafted by the National Conference of Commissioners on Uniform State Laws, http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf.
[53] *Id.*

differently, given the "complicated legal, scientific, moral, and ethical issues which may arise."[54] To date, eight states explicitly prohibit experimentation on aborted infants: Alabama, Arizona, Idaho, Indiana, North Dakota, Ohio, Oklahoma, and South Dakota. In other states, restrictions on the use of aborted infants' remains for research are implicit.

For instance, New Mexico's Jonathan Spradling Revised Uniform Anatomical Gift Act (Spradling Act)[55] is based on the UAGA.[56] The Spradling Act was enacted in 2007 to replace the State's existing Anatomical Gift Act[57] with provisions mirroring the UAGA.[58] In their new law, New Mexico decided to follow the suggestion in the UAGA to treat aborted fetuses differently: "'decedent' means a deceased individual whose body or part is or may be the source of an anatomical gift." It "includes a stillborn infant and . . . a fetus but [does] not includ[e] a fetus that is the subject of an indueed abortion."[59]

Further, the Spradling Act provides that the Act "applies to an anatomical gift or amendment to, revocation of or refusal to make an anatomical gift, whenever made."[60] In other words, all anatomical gifts in the State of New Mexico must comply with this act, and the bodies or body parts of aborted infants cannot be anatomical gifts.

The Panel learned, however, that the University of New Mexico (UNM) and the late-term abortion clinic Southwestern Women's Options (SWWO) have an extensive history in which SWWO provided fetal tissue to UNM researchers. SWWO's provision and UNM's acquisition of and research using aborted infant remains appear to violate the Spradling Act. Any consents ostensibly obtained by SWWO from mothers of aborted infants do not validate the donation of their infants' remains for research, because under the Spradling Act the bodies or parts of aborted infants may not be anatomical gifts.

3. NIH Revitalization Act of 1993

Under the NIH Revitalization Act of 1993, the Secretary of the Department of Health and Human Services (HHS) is permitted "to conduct or support research on the transplantation of human fetal tissue for therapeutic purposes," including tissue from aborted infants. The law places numerous requirements on the acquisition of fetal tissue and on fetal tissue research, including a requirement that the infant's mother provide written consent. Further, when tissue is obtained from aborted infants, a mother's consent to donate her infant's remains must *follow* her consent to the abortion procedure. The law also prohibits the "alteration of the timing, method, or procedures used to terminate the pregnancy . . . solely for the purposes of obtaining the tissue," and requires abortion providers to perform the abortions in accordance with "applicable State law."[61]

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[54] *Id.*
[55] N.M. Stat. Ann. § 24-6B-1, *et seq.*
[56] Revised Uniform Anatomical Gift Act.
[57] N.M. Stat. Ann. § 24-6A-1 *et seq.*
[58] *See* Fiscal Impact Report, Revised Uniform Anatomical Gift Act 3 (Mar. 14, 2007), https://www.nmlegis.gov/Sessions/07%20Regular/firs/HB1276.pdf.
[59] N.M. Stat. Ann. § 24-6B-2 (emphasis added).
[60] N.M. Stat. Ann. § 24-6B-3.
[61] 42 U.S.C. § 289g-1.

Additionally, the Act provides that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Further, the solicitation or acceptance of tissue as directed donation for use in transplantation is prohibited. Persons or entities "involved or engaged in interstate commerce" may not "solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue." Violations of this law can result in a fine or imprisonment for up to 10 years. "Valuable consideration" is defined to exclude "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[62]

Laws regulating the donation of human organs, including human fetal organs, are relevant for the Panel's investigation, given the possibility that both tissue procurement businesses (TPBs) and abortion providers are profiting from fetal tissue procurement. During the Panel's April 20, 2016, hearing, *The Pricing of Fetal Tissue*, Panel members asked witnesses to examine evidence that payments paid by customers to a TPB for fetal tissue exceeded costs incurred by the business by a factor of 300 to 700 percent. Further, the evidence *did not* demonstrate that in many instances the "compensated" abortion clinics incurred any actual costs.[63]

Witness Brian Lennon, a former federal prosecutor, stated that he "didn't see [evidence] in any of the [hearing] exhibits" that abortion clinics had reasonable costs associated with fetal tissue donation.[64]

C. Laws Protecting Late-Term and Born-Alive Infants

House Resolution 461 provided the Panel with jurisdiction to review "[t]he practice of providers of second and third trimester abortions, including partial birth abortion procedures that may lead to a child born alive as a result of an attempted abortion," as well as "[m]edical procedures for the care of a child born alive as a result of an attempted abortion." The panel investigated these issues in the context of two federal laws—the Born-Alive Infants Protection Act and the Partial-Birth Abortion Ban Act.

1. Born-Alive Infants Protection Act (BAIPA)

President George W. Bush signed the Born-Alive Infants Protection Act (BAIPA)[65] in 2002, which passed by voice vote in the House of Representatives and with unanimous support in the Senate. BAIPA clarifies that for purposes of all federal laws, the terms "person," "human being," "child," and "individual" include every infant who is born alive, regardless of whether that birth is the result of labor, cesarean section, or induced abortion. BAIPA *does not* contain its own criminal penalties or any other enforcement mechanism to hold abortion providers accountable who fail to provide medical attention and care to infants born alive during an

[62] 42 U.S.C. § 289g-2.
[63] *See generally The Pricing of Fetal Tissue: Hearing Before the Select Investigative Panel, The Comm. on Energy and Commerce*, 114th Cong. (2016).
[64] *Id.* at 97.
[65] 1 U.S.C. § 8.

abortion or attempted abortion.

The "right to an abortion" does not equal the right to a dead child. Through the enactment of BAIPA, the United States Congress recognized that the right to abortion has limits, and is not an absolute, ever-expanding right. In particular, the right to abortion does not extend so far as to justify the denial of fundamental civil rights and protections to born, living human children.

During the Panel's investigation, staff reviewed tissue procurement notes, email exchanges among researchers, TPBs and abortion clinics, invoices, and more—all indicating that researchers want fetal tissue from late-gestation infants that has not been tainted by feticidal agents (*e.g.*, digoxin).[66] The Panel also learned that abortion providers may modify abortion procedures, in apparent violation of the law, to increase the odds of getting an intact infant cadaver (*e.g.*, increase the number of laminaria placed in a patient's cervix to achieve greater dilation).[67] Clearly, these factors increase the likelihood that unborn infants are born alive during late second trimester abortions, and raise the question whether these infants' civil rights are recognized by abortion providers.

[PP Witness #3] acknowledged that "a practitioner who does not intend to do an intact procedure could nonetheless have an intact delivery that was not intended."[68] Further, interviews with second-trimester abortion providers revealed that, while they deny delivering live infants during abortion procedures, they are inadequately prepared to care for an infant if a live birth were to occur. When asked what Planned Parenthood would do if an infant was born alive during an abortion procedure, [PP Witness #1] stated bluntly:

> I can tell you that none of our Health Centers provide obstetrics care. So they don't deliver babies. So they don't have anyone who can provide care, nor do they know what that care is. . . . We don't deliver babies at Planned Parenthood. . . . [O]ur affiliates don't provide obstetrical care. So therefore, they don't know how to manage a term infant or a premature infant.[69]

When Panel staff asked whether "the protocol [should] be to call an ambulance right away" if a premature infant were born alive during an abortion, [PP Witness #1] stated "[s]o there's no protocol for this. I'm not going to sit here and write a protocol."[70]

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[66] *See, e.g.*, Documents produced by the University of New Mexico: procurement notes stating "clinic now uses digoxin only at 20 weeks" [UNM 00049]; procurement notes lamenting that 25-week aborted infant "treated" with digoxin: "heart mushy; GI discolored +liver; skin loose; eyes discolored red" [UNM 00004]; heavily redacted email exchange, where UNM employee states that they will try to get later gestation lung; sometimes they can get up to 20-22 weeks, but unusual "these days" to get non-digoxin-exposed samples beyond 18 weeks [UNM 00910], Exhibit 2.3.

[67] *See generally Interview of [PP Witness #1], before the Select Investigative Panel, Comm. on Energy and Commerce*, 114th Cong. (unedited transcript) (Oct. 6, 2016).

[68] *Interview of* [PP Witness #3], *before the Select Investigative Panel, Comm. on Energy and Commerce*, 114th Cong. 46 (unedited transcript) (Nov. 1, 2016).

[69] *Interview of [PP Witness #1]*, at 223-24.

[70] *Interview of [PP Witness #1]*, at 225-27. At that time, [PP Witness #1]'s, attorney asked for a break. Upon returning, [PP Witness #1] stated that if an infant were born with signs of life, she "would call an ambulance and

2. Partial-Birth Abortion Ban Act (PBA)

President George W. Bush signed the **Partial-Birth Abortion Ban Act (PBA)** on November 5, 2003.[71] In 2007, the Act was upheld by the United States Supreme Court in *Gonzales v. Carhart*.[72] The PBA prohibits the abortion procedure known as "partial-birth abortion," or "intact dilation and extraction," described as when the abortion provider:

> (A) deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and
>
> (B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus. . . .

At least 19 states have laws mirroring the federal PBA.[73] Because researchers desire to obtain intact fetal cadavers and organs, as discussed above, the Panel investigated whether abortion providers may be using the partial-birth abortion procedure in violation of federal and/or state law.

D. Laws Related to Public Funding of Fetal Tissue Research and Abortion Providers

1. NIH Grants

On October 4, 2000, the U.S. GAO reported that the National Institutes of Health (NIH) is the only federal agency under the Subcommittee on Labor, Health and Human Services, and Education jurisdiction that sponsors research using human fetal tissue.[74] NIH spent $76 million on human fetal tissue research in FY2014, and will spend approximately $76 million in FY2015 and $77 million in FY2016.[75] In addition to broader reporting requirements regarding "activities conducted or supported by the NIH, the Director of NIH is required to submit to Congress an annual report that describes how NIH and its agencies "store and track human tissue samples."[76] (For a detailed examination of NIH grants, please see Chapter IX.)

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give the fetus comfort care until the ambulance arrived if it was viable or looked like [sic] a periviable" or would "just give it comfort care and let it expire" if the infant were "nonviable."

[71] 18 U.S.C. § 1531.

[72] 550 U.S. 124 (2007).

[73] *See* Guttmacher Institute, *Bans on Specific Abortion Methods Used After the First Trimester* (Nov. 1, 2016), https://www.guttmacher.org/state-policy/explore/bans-specific-abortion-methods-used-after-first-trimester.

[74] GAO letter to Arlen Specter, Chairman, Subcomm. on Labor, Health and Human Services, and Education, Committee on Appropriations 2 (Oct. 4, 2000).

[75] Kristin Finklea, et al., Cong. Research Serv., R44129, Fetal Tissue Research: Frequently Asked Questions 1 (July 15, 2015) (based on search criteria entered at http://report.nih.gov/categorical_spending.aspx).

[76] PL 109-482.

2. Federal Funding for Abortion Providers

H. Res. 461 also gave the Panel jurisdiction to review federal funding and support for abortion providers. Congress has included restrictions on abortion funding in the HHS appropriations acts since fiscal year (FY) 1977. These restrictions, commonly known as the Hyde Amendment, prohibit the use of federal and state matching Medicaid funds[77] for most abortions. However, Congress permits abortion funding in specific circumstances that have changed periodically since enforcement began August 4, 1977, including when a pregnancy endangers a mother's life or health, and when the pregnancy resulted from rape or incest. In certain fiscal years, Congress required documentation and reporting to prove that a woman's circumstances fit the exceptions permitting abortion coverage. States may pay for abortions with state or local funds (*not* state matching Medicaid funds) allocated for health benefits or services.[78]

Other sources of federal funding may be used to pay for abortions; however, they are generally subject to restrictions mirroring the Hyde Amendment.[79] Hyde-like language exists "in the appropriations measures for foreign operations, the District of Columbia, the Treasury, and the Department of Justice."[80] Further, funds available to the Department of Defense (DOD) and the Indian Health Services (IHS) are limited by codified restrictions.[81]

While Congress has long limited the use of federal tax dollars to directly pay for abortions, abortion providers receive significant public funding ostensibly for other purposes. Sources of funding for "reproductive health services" include Medicaid (family planning), Title X of the Public Health Service Act, the Federal Health Center Program, The Ryan White HIV/AIDS program, the National Breast and Cervical Cancer Early Detection Program, Sexually Transmitted Diseases Prevention Grants, Title V Maternal and Child health Block Grant, Teen Pregnancy Prevention Program, and the Social Services Block Grant Program.[82] Additionally, many states and localities provide funding for reproductive health services.

a) Medicaid

Medicaid accounts for 75% of U.S. public expenditures for "family planning services"—up from 20% in 1980.[83] Medicaid reimburses providers for contraceptive items and procedures and related services, with the federal government paying 90% of the cost (versus 50% to 75% for

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[77] "Medicaid provides health coverage to millions of Americans, including . . . pregnant women. . . . Medicaid is administered by states, according to federal requirements. The program is funded jointly by states and the federal government." Medicaid.gov, overview, https://www.medicaid.gov/medicaid-chip-program-information/medicaid-and-chip-program-information.html.

[78] *See generally* FY 2017 Moyer Material, Submitted by the Office of the Assistant Secretary for Financial Resources, U.S. Depart. of Health and Human Services, Addendum: Abortion-Related Reporting 1-8 (2016).

[79] *See generally* Elayne J. Heisler, et al., Cong. Research Serv., R44130, *Federal Support for Reproductive Health Services: Frequently Asked Questions* (Aug. 24, 2016).

[80] *Id.* at 2.

[81] *Id.*; 10 U.S.C. § 1093 (DOD) and 25 U.S.C. § 1676 (IHS).

[82] *See generally Federal Support for Reproductive Health Services: Frequently Asked Questions.*

[83] *See, e.g.*, Guttmacher Institute, *Publicly Funded Family Planning Services in the United States*, https://www.guttmacher.org/fact-sheet/publicly-funded-family-planning-services-united-states.

most other services) and states paying 10%, and with no out-of-pocket costs for beneficiaries.[84] Medicaid enrollees are permitted to receive family planning care from "qualified providers" of their choice, regardless of whether the providers are in their health plans' network. That family planning provider is then reimbursed by the state or by the plan.[85]

In FY 2010, federal and state[86] public expenditures for family planning services alone totaled $2.37 billion.[87] While not all recipients of this funding perform abortions,[88] the nation's largest abortion provider, Planned Parenthood, provides an excellent study of the impact of public funding on the abortion industry.[89] During fiscal year 2015, 43% of Planned Parenthood's revenue derived from "government health services grants & reimbursements," at a price tag of $553,700,000.[90]

Further, while abortion providers are not permitted to receive reimbursement *for abortion* from Medicaid, former employees of Planned Parenthood have testified that Planned Parenthood would separate out charges for services and products rendered in connection with abortions, such as office visits, ultrasounds, Rh factor tests, lab work, general counseling, and abortion aftercare, and submit those "fragmented" or "unbundled" charges as claims for Medicaid reimbursement.[91]

In fact, the Charlotte Lozier Institute and Alliance Defending Freedom have documented that—based on 51 known external audits or other reviews of Planned Parenthood affiliates' financial data and practices, and 61 federal audits of state family planning programs by HHS-OIG—Planned Parenthood affiliates have overbilled $132.4 million in Medicaid and other healthcare funding programs.[92] These audit results are troubling, given their limitations in scope,

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[84] *See, e.g., id.*; *Federal Support for Reproductive Health Services: Frequently Asked Questions.*

[85] *Federal Support for Reproductive Health Services: Frequently Asked Questions.*

[86] State funding accounted for 12 percent of the total. Guttmacher Institute, *Publicly Funded Family Planning Services in the United States*, https://www.guttmacher.org/fact-sheet/publicly-funded-family-planning-services-united-states.

[87] *Publicly Funded Family Planning Services in the United States.*

[88] *Publicly Funded Family Planning Services in the United States.* In 2010, subsidized family planning services were provided at 8,409 "safety-net health centers"—38% were federally qualified health centers; 29% were health department clinics; 16% were other clinics; 10% were Planned Parenthood centers; and 8% were hospital clinics.

[89] Planned Parenthood is the largest abortion provider in the U.S., performing more than 300,000 abortions per year, or approximately 1 in 3. Americans United for Life, *The New Leviathan: The Mega-Center Report—How Planned Parenthood has Become Abortion, Inc.* 4 (2015), http://www.aul.org/wp-content/uploads/2015/06/AUL-Mega-Center-Report-06-24-2015.pdf (citing PPH Annual Reports for 2012, 2013, and 2014 at Planned Parenthood of the Heartland, Publications, http://www.plannedparenthood.org/planned-parenthood-heartland/who-we-are/publications).

[90] Planned Parenthood Federation of America, Annual Report, 2014-2015, at 32-33, https://www.plannedparenthood.org/files/2114/5089/0863/2014-2015_PPFA_Annual_Report_.pdf.

[91] Americans United for Life, *The Planned Parenthood Exhibits: The continuing case for investigating the nation's largest abortion provider* Exhibit 17 (2012).

[92] Charlotte Lozier Institute and Alliance Defending Freedom, *Profit. No Matter What.* (Nov. 1, 2016). In addition to "fragmenting" and "unbundling" abortion services in violation of the Hyde Amendment, Planned Parenthood affiliates were found by audit: "Dispensing prescription drugs, including oral contraceptives, without an authorizing order by a physician or other approved healthcare practitioner; Dispensing prescription drugs, including oral contraceptives, to patients who have moved or have not been seen by the clinic for more than a year; Billing in excess of actual acquisition cost or other statutorily approved cost for contraceptive barrier products, oral contraceptives, and emergency contraceptive-Plan B (i.e., § 340B drugs) products; Billing for services that were not medically necessary, including services for men and for women who were already pregnant, sterilized, or

detail, and timeframe; in fact, of 57 U.S. Planned Parenthood affiliates, only 19 have been audited.[93]

Under federal law, healthcare providers participating in Medicaid are required to return overpayments within sixty days of identification.[94] State Medicaid agencies are also required to return overpayments and have up to a year to make collections before they are penalized by the federal government.[95]

The United States Supreme Court has held that it is permissible for a state to engage in unequal subsidization of abortion and other medical services to encourage alternative activity deemed in the public interest.[96] However, courts and the executive branch have largely thwarted efforts to prevent abortion providers from subsidizing abortion and other services with taxpayer funding.

The Obama Administration has denied or threatened to deny federal Medicaid funding to states that have attempted to withhold Medicaid reimbursement from abortion providers. Further, the Seventh and Ninth Circuits have interpreted Medicaid's "free choice of provider"[97] provision—guaranteeing Medicaid recipients' freedom to choose their family planning providers—as a legal impediment to prohibiting abortion providers from receiving federal Medicaid funding.[98]

However, in *Planned Parenthood v. Indiana*, the Seventh Circuit *upheld* Indiana's prohibition on abortion providers receiving funding through the federal Disease Intervention Services agency ("DIS"), for the diagnosis and monitoring of sexually transmitted diseases. The Seventh Circuit explained that the key difference between the provision upheld and the provision struck down was that the DIS program did *not* have a federal statutory limitation (similar to Medicaid's "free choice of provider" provision) on how states could determine eligibility.[99]

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postmenopausal; Billing for services that were not actually rendered; Duplicate billing for examinations and products, including billing products and services already billed as part of a service package, as fee for service; Incorrectly coding and billing services; Inadequate record-keeping, including lacking documentation to support the service billed and paid and not signing medical entries; and Failing to pay the bills for which an affiliate had already been reimbursed with taxpayer funds."

[93] *See id.*

[94] SSA Sec. 1128J(d).

[95] SSA Sec. 1903(d)(2).

[96] Further, the decision not to fund abortion places no governmental obstacle in the path of a woman who chooses to terminate her pregnancy. *See Rust v. Sullivan*, 500 U.S. 173, 201 (1991). The Court has repeatedly affirmed the constitutionality of federal and state restrictions on public funding for abortions. *See, e.g., Harris v. McRae*, 448 U.S. 297 (1980) (holding that the government may rationally distinguish between abortion and other medical procedures because "no other procedure involves the purposeful termination of a potential life").

[97] 42 U.S.C. § 1396a(a)(23)(B). A state may establish "reasonable standards relating to the qualifications of providers" and may exclude healthcare providers under certain circumstances: "[i]n addition to any other authority, a State may exclude an individual or entity . . . for any reason for which the Secretary [of HHS] could exclude the individual or entity from participation." 42 C.F.R. § 431.51(c)(2); 42 U.S.C. § 1396a(p)(1)).

[98] *Planned Parenthood v. Indiana*, 699 F.3d 962 (7th Cir. 2012) (invalidating an Indiana law); *Planned Parenthood v. Betlach*, 727 F.3d 960 (9th Cir. 2013) (invalidating an Arizona law).

[99] *Planned Parenthood v. Indiana*, 699 F.3d 962, 985 (7th Circ. 2012).

Legislative history demonstrates that states should have the power to exclude providers for *any reason/basis* under its state laws: "This provision is not intended to preclude a State from establishing, under State law, any other bases for excluding individuals or entities from its Medicaid program."[100] Also, the First Circuit held that the language of Medicaid's exclusion provision "was intended to permit a state to exclude an entity from its Medicaid program for *any* reason established by state law."[101]

b) Title X

Title X is the only federal grant program dedicated solely to providing family planning and related preventive care and is viewed as setting the standard for publicly funded family planning services. Priority is given to low-income families. Title X provides that "none of the funds appropriated ... shall be used in programs where abortion is a method of family planning."[102] Public and private entities may obtain grants.

Ten percent of U.S. public expenditures for family planning client services are through Title X.[103] This is a 71% drop since 1980. Title X funding is valued because it provides more flexibility than Medicaid. The grants are used to maintain a network of "family planning Centers." The Reagan administration's strict regulations on Title X funding, designed to ensure the funds were not being used to subsidize abortion, were upheld by the Supreme Court in *Rust v. Sullivan*;[104] however, they are not in effect today.

Since 2011, numerous states have enacted laws requiring subrecipients of Title X funds to provide comprehensive healthcare to patients and/or refrain from performing abortions. In response, the federal government is actively circumventing the Title X prioritization laws in at least eight states by directly contracting with private entities such as Planned Parenthood.

Further, on Sept. 9, 2016, HHS issued a proposed rule stating that "[n]o recipient making sub awards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons unrelated to its ability to provide services effectively."[105] In the proposed rule background, HHS states that "13 states have placed restrictions on or eliminated sub awards with specific types of providers. . . ."[106]

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[100] S. Rep. No. 100-109, at 20 (1987).
[101] *First Medical Health Plan v. Vega-Ramos*, 479 F.3d 46, 53 (1st Cir. 2007) (emphasis in original).
[102] 42 U.S.C. § 300a-6.
[103] *Publicly Funded Family Planning Services in the United States*. Other family planning funding: 75% - Medicaid; 12% - state-only sources; 3% - other federal sources.
[104] 500 U.S. 173 (1991).
[105] Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients, 81 Fed. Reg. 173 (proposed Sept. 7, 2016) (to be codified at 42 C.F.R. pt. 59).
[106] *Id.*

III. Panel Hearings

The Panel held two public hearings to examine critical issues within its jurisdiction. In the first hearing on *Bioethics and Fetal Tissue*, the Panel noted that there have been several government-sponsored discussions on bioethics, but none directly on the transfer of fetal tissue since the 1980s. The hearing revealed substantial concern about the consent process for the donation of human fetal tissue used by abortion clinics and procurement businesses. Evidence revealed that self-interested staff, whose pay depends on the numbers of specimens donated, were assigned to obtain consent from patients. Additional evidence showed that tissue technicians and the abortion clinics violated the patient's privacy rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Still other evidence revealed that some middleman companies misrepresented that the consent forms and methods of tissue harvesting comply with federal regulations regarding Institutional Review Boards (IRBs). This evidence points toward conduct focused on profit and not on patient welfare.

The Panel's next hearing, *The Pricing of Fetal Tissue*, sought the judgment of seasoned federal prosecutors to compare the federal statute prohibiting profit from fetal tissue sales with the first tranche of materials from the investigation. Two former U.S. attorneys and a senior federal litigator agreed that based on the materials presented to them, they would open a case against a middleman company. The former prosecutors also suggested that accounting and bank records would be critical to understanding whether there was a violation of federal law. Minority witnesses agreed with this approach and urged the Panel to obtain such records.

A. Bioethics and Fetal Tissue

On March 2, 2016, the Panel held a hearing entitled *Bioethics and Fetal Tissue*. The hearing focused on ethical issues raised as a result of information recently made public about fetal tissue donations, transfer of fetal tissue, and use of fetal tissue by research institutions. The witnesses helped the Panel understand the ethical questions, both on theoretical and practical levels, which arise when fetal tissue is acquired and used in biomedical research.

Bioethics has its origins as a field of academic inquiry in the early 1960s due to extraordinary advances and development in American medical knowledge and practice. Organ transplantation, kidney dialysis, respirators, and intensive care units made possible medical procedures never before imagined. The first heart transplant raised ethical questions relating to the sources of organs for transplantation, how they would be allocated, and payment for these procedures.

Public debates took place and, in response, scholars and academics began to think and write about these issues, and scholars began to fuse theoretical ethics with applied or practical ethics. Since that time, continuing biomedical advances have presented bioethical questions that need to be confronted and addressed by societies.

Today's headlines are full of announcements and predictions that a few short years ago were the subject of speculative fiction. Organ reconstitution, three-parent children, personalized medicine, organ cloning, chimeras, gene therapy and editing, and bioinformatics are all recent

subjects discussed by professionals and the public. The current director of the National Institutes of Health has proposed compiling DNA information to help inform medical decisions and therapies. While these therapies further knowledge of biomedical and scientific information related to medical treatments and therapies, they also present broader ethical questions.

Paige Comstock Cunningham, Executive Director for The Center for Bioethics & Human Dignity, told the Panel that "you cannot take a life and then give away the body. Participants in elective abortion, including the mother, are morally disqualified from consenting to donating the body, organs, or tissue of the now dead fetus for research purposes."[107]

Dr. Patrick Lee, a professor at the Center for Bioethics at Franciscan University of Steubenville, spoke of his concern that "governmental funding of abortion providers and the use of fetal tissue from elective abortions involve profound dehumanization of unborn human beings and are grave injustices."[108]

During the hearing, Majority and Minority Members and witnesses discussed current bioethical questions regarding the use of fetal tissue in scientific research. One concern raised by the Minority Members of the Panel and the Minority witnesses was that stopping the use of fetal tissue in scientific research, such as developing a cure for the Zika virus, would delay the finding of a cure. Rep. Jan Schakowsky (IL-9) asked Dr. Lawrence Goldstein, a minority witness, "Would not having fetal tissue as a resource in this study potentially delay finding a cure?" Dr. Goldstein replied, "It would absolutely delay it."[109]

However, later in the hearing in an exchange with Dr. Goldstein, Rep. Andy Harris (MD-1), who is also a physician, emphasized that sometimes delays occur in order to ensure that research, especially research conducted on human subjects, is done ethically and safely. Addressing Dr. Goldstein, Rep. Harris stated, "[Y]ou have suggested that anything that slows this process down is a bad thing. You kind of suggested that. . . . How long does it take your IRB to approve, normally? Mine took months. I know exactly why you are laughing. It can take months or even a year, can't it?"[110] Rep. Harris summarized their discussion by stating that the United States has already decided "that it is all right to slow down life-saving research when it involves humans for ethical reasons because we have a national policy that you have to have an IRB."[111] Furthermore, the idea that not having access to fetal tissue would delay the discovery of a cure is mere speculation, especially since fresh fetal tissue has not been successful in curing diseases. Dr. Goldstein conceded Rep. Harris' point.

Also during the hearing, Members of the Panel expressed their deep concern regarding the issue of consent and minors. Rep. Mia Love (UT-4) stated: "So imagine [a] 14-year-old going into a clinic to undergo a very invasive procedure without someone there that she trusts to walk her through, to make sure that she is not being taken advantage of, to make sure that she is making the right decision."[112] Rep. Love asked, "How can anyone be sure that a minor, under

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[107] *Bioethics and Fetal Tissue*, at 24 (Mar. 2, 2016) (unedited transcript).
[108] *Id.* at 98.
[109] *Id.* at 120.
[110] *Id.* at 138.
[111] *Id.* at 139.
[112] *Id.* at 86-87.

difficult circumstances, fully understand[s] the long-term repercussions behind [her] decision when the current law wouldn't even allow that minor to get behind the wheel of a vehicle?"[113] Dr. Gerald Kevin Donovan, a witness at the hearing, agreed that this presented a troubling problem.[114]

Dr. Kathleen Schmainda, a Professor at the Medical College of Wisconsin, told the Panel that "the repeated assurances that proper ethical guidelines are in place to avoid the connection between abortion and subsequent research are entirely inadequate."[115]

Members and witnesses came to a bipartisan agreement on several points:

Common Ground →	No one should profit from the sale of fetal tissue.[116]
	Inappropriate to get pregnant in order to donate fetal tissue for research.[117]
	A form used by an abortion clinic to obtain a woman's consent to donate fetal tissue contained inappropriate statements and should not have made it past an IRB.[118]
	No cures have been found that require fetal tissue.[119]
	Fetal tissue should not be used for cosmetics or taste testing.[120]
	It is a moral decision for a woman to decide whether to make the fetal tissue donation.[121]

[113] *Id.*
[114] *Id.*
[115] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. 105 (Mar. 2, 2016) (unedited transcript).
[116] *Id.* at 161.
[117] *Id.* at 37-38.
[118] *Id.* at 149.
[119] *Id.*
[120] *Id.* at 37, 89, 136-37, 163 (Ms. Alta Charo, a minority witness, stated, "Well, using any tissue, fetal or adult, I find the cosmetic uses in Hollywood sometimes to be so frivolous, I would be perfectly happy to see us abandon them.").
[121] *Id.* at 140.

Amazing scientific and biomedical advances are continuously being discovered and developed. Congress, research institutions, and the medical community must continue to work together to promote medical advancements while simultaneously ensuring that laws and regulations on ethics remain up to date. Whenever biomedical research is conducted on human subjects, the work must be ethical and preserve the dignity of the human beings who made these advancements possible.

B. The Pricing of Fetal Tissue

On April 20, 2016, the Panel held a hearing on *The Pricing of Fetal Tissue*. During the hearing, the Panel examined documents revealing that abortion clinics and Tissue Procurement Businesses (TPBs) may have violated federal law by the payments they collected from the sale of fetal tissue. At the core of the Panel's investigation is a federal statute, 42 U.S.C. § 289g-2, which prohibits the transfer of any human fetal tissue for valuable consideration. The statute states that reasonable costs include transportation, implantation, processing, preservation, quality control, and storage—none of which it appears the abortion clinics did. Documents also show that payments made by the customer to the procurement business appear to exceed the costs incurred on the procurement business by a factor of 300 to 400 percent.[122]

Witnesses at the hearing were presented with a sample of the accounting records from StemExpress and several abortion clinics. The witnesses for the hearing included three former prosecutors who all agreed that the documents made the case that 42 USC § 289g-2 may have been violated and that further investigation was warranted. All witnesses at the hearing agreed that the Panel should review all bank and accounting records in order to gain a complete understanding.

When asked by Rep. Joe Pitts (PA-16) what communications or information should be sought to learn whether the intent of the procurement business and the abortion clinic was to profit from the sale of fetal tissue, former U.S. Attorney Kenneth Sukhia said, "I would also want to know what communications occurred between – other communications, email and so forth, back and forth between those people. We would seek those items as well, and of course the accounting records."[123]

Brian Lennon told the Panel that "a competent and ethical federal prosecutor could establish probable cause that both the abortion clinics and the procurement businesses [that the Panel was investigating] violated the statute, aided and abetted one another in violating the statute, and likely conspired together to violate the statute." Lennon went on to say "in my opinion, there is proof without a reasonable doubt."[124] He told the Panel that "a forensic accounting would be essential to breaking down the company's financials."[125]

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[122] *See generally The Pricing of Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. (Apr. 20, 2016) (unedited transcript).
[123] *Id.* at 147.
[124] *Id.* at 52-53.
[125] *Id.* at 56-57.

Fay Clayton, a lead Democrat witness, said she'd "have them [StemExpress] come in, put them under oath . . . and ask them how did you come up with this charge?"[126] Clayton said she would "ask them, in each particular case, what aspect of the actual costs does a particular clinic incur? For example, does the clinic provide space? Does the clinic, as we have seen in your charts, provide the blood draws which requires a technician, perhaps a nurse, materials? Does the clinic have to do paperwork? And, if so, how much? And, therefore, how much of the actual reasonable cost is incurred by the clinic itself as opposed to by the procurement business?"[127]

Former U.S. Attorney Michael Norton told the Panel that he "would get forensic accounting."[128] "I would get all of the financial records. I would get the profit and loss statements, the income and expense statements, and I would get people under oath before a grand jury,"[129] Norton said.

Catherine Glenn Foster told the Panel that there were two things she would specifically seek among other documents:

> First of all, financial records. That is something that must be brought to light. And, second, women of every generation are unique human beings who can speak for themselves, but the baby body parts profiteers have created a market in which their profits rise if they pressure and coerce women into signing donation consent forms.[130]

Based on the consensus reached by witnesses at the hearing, the Panel has worked to acquire and further investigate the details of accounting records, accounts payable, and cash transfers of abortion businesses, fetal tissue procurement organizations, and related entities to determine whether or not someone made a profit.

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[126] *Id.* at 144.
[127] *Id.* at 145.
[128] *Id.* at 146.
[129] *Id.*
[130] *Id.*

IV. Criminal and Regulatory Referrals

15 Criminal & Regulatory Referrals

The Select Investigative Panel has made numerous criminal and regulatory referrals and investigations are underway around the nation.

1) The Panel discovered that the University of New Mexico may have been violating its state's Anatomical Gift Act by receiving tissue from a late-term abortion clinic (Southwestern Women's Options). Referred to the Attorney General of New Mexico.

2 & 3) The Panel conducted a forensic accounting analysis of StemExpress' limited production and determined that it may have been profiting from the sale of baby body parts. Referral sent to El Dorado, California, District Attorney, and the U.S. Department of Justice.

4) The Panel learned that StemExpress and certain abortion clinics may have violated the HIPAA privacy rights of vulnerable women for the sole purpose of increasing the harvesting of fetal tissue to make money. Referred to the U.S. Department of Health and Human Services.

5) The Panel uncovered evidence showing that StemExpress may have violated federal regulations governing Institutional Review Boards (IRBs). Referred to the U.S. Department of Health and Human Services.

6) The Panel discovered that an abortion clinic in Arkansas may have violated the law when it sent tissue to StemExpress. Referred to the Attorney General of Arkansas.

7) The Panel discovered that DV Biologics, another tissue procurement company, may have been profiting from the sale of fetal tissue, and was not collecting California sales tax from purchasers of the baby body parts. The Orange County District Attorney has filed a lawsuit and the Panel sent a supplemental referral.

8) The Panel learned that Planned Parenthood Gulf Coast may have violated both Texas Law and U.S. Law when it sold fetal tissue to the University of Texas. Referred to the Texas Attorney General.

9) The Panel learned that Advanced Bioscience Resources appeared to have made a profit when it sold tissue to various universities. Referred to the District Attorney for Riverside County, California.

10) The Panel discovered that an abortion clinic in Florida, at least in part through its relationship with StemExpress, may have violated various provisions of federal and state law by profiting from the sale of fetal tissue. Referred to the Attorney General of Florida.

11 & 12) The Panel has uncovered evidence from former employees and a patient of a late-term abortionist in Texas alleging numerous violations of federal and state law at one or more of the

practitioner's clinics. The allegations include eyewitness accounts of the doctor killing infants who show signs of life both when partially outside the birth canal, in violation of the Partial-Birth Abortion Ban Act, and after they are completely outside the birth canal, in violation of the Born-Alive Infants Protection Act and Texas murder statutes. Referred to the Texas Attorney General, and the U.S. Department of Justice.

13) The Panel made a supplemental referral to the Attorney General of New Mexico based on information produced in document productions by the University of New Mexico (UNM) and Southwestern Women's Options (SWWO), deposition testimony by Doctor #5, and a complaint and affidavit with supporting documents submitted by a former patient at SWWO. It details the alleged failure of SWWO and UNM to provide informed consent to women prior to using tissue from abortions for research at the university.

14) The Panel has discovered information that StemExpress may have destroyed documents that were the subject of congressional inquiries, document request letters, and subpoenas, in violation of 18 U.S.C. § 1519. Referred to the U.S. Department of Justice.

15) Over the course of its investigation, the Panel has uncovered documents and received testimony from confidential informants indicating that several entities, including four Planned Parenthood clinics and Novogenix, may have violated federal law, specifically Title 42 U.S.C. § 289g-2, which forbids the transfer of fetal tissue for valuable consideration. Referred to the U.S. Department of Justice.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 Rayburn House Office Building
Washington, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

June 23, 2016

VIA EMAIL

The Honorable Hector H. Balderas, Jr.
Attorney General of New Mexico
408 Galisteo Street
Villagra Building
Santa Fe, NM 87501

Dear Attorney General Balderas:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue. The Panel's work implicates 42 U.S.C. § 289g-2, which forbids the transfer of fetal tissue for valuable consideration.

Section 289g-2 requires that safeguards be in place, including a concern that too close a relationship might be formed between an abortion clinic and researchers. In the course of its inquiry, the Panel uncovered just such a relationship between the University of New Mexico ("UNM") and Southwestern Women's Options ("SWWO"), a clinic located one mile from UNM that provides abortions through all three trimesters of pregnancy. We understand that SWWO is the sole provider of fetal tissue to UNM.

Through its investigation, the Panel has discovered that personnel within UNM's hospital and medical school have aggressively engaged in expanding abortion in New Mexico through the offices, personnel, and resources of UNM. In particular, leadership personnel at UNM: (1) expanded UNM's role in training new abortion doctors; (2) expanded UNM's referral for abortion services to outside clinics, including the clinic from which it obtained fetal tissue; (3) initiated the practice of sending UNM faculty and residents to an abortion clinic during its transition from one owner to another; (4) expanded the faculty of UNM by providing "volunteer faculty" status to local abortionists; (5) supplied residents and fellows to perform abortions for SWWO during the period that UNM was obtaining fetal tissue from that clinic; and (6) leveraged their status to organize UNM

employees and students for partisan political activities. UNM has stated that the fetal tissue transferred from SWWO is of great value to its research department.

Additionally, documentation obtained by the Panel in the course of its investigation reflects that the transfer of fetal tissue from SWWO to UNM for research purposes is a systematic violation of New Mexico's *Jonathan Spradling Revised Uniform Anatomical Gift Act* (*Spradling Act*). **These violations occurred as UNM personnel procured fetal tissue from patients at SWWO for research by UNM entities.**

A detailed report accompanying this letter describes the Panel's discovery that transfers of value to SWWO from UNM occurred within a context of aggressive abortion advocacy. We appreciate your swift attention to the serious and systematic violations of law committed by the University of New Mexico and Southwestern Women's Options. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov, or Mary Harned, at (202) 480-7160, Mary.Harned@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chairman
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Investigative Panel

The Honorable Susana Martinez
Governor of New Mexico

The Honorable John A. Sanchez
Lieutenant Governor of New Mexico

The Honorable Steve Pearce
Second Congressional District, New Mexico

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 2, 2016

VIA EMAIL AND FIRST CLASS MAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC ("StemExpress"), a firm that procures fetal tissue from abortion clinics and transfers it to research customers, violated various provisions of federal and state law, including but not limited to 42 U.S.C. § 289g-2 and Cal. Penal Code § 367f, which forbid the transfer of fetal tissue for valuable consideration.

StemExpress' Business Model and Growth Strategy

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Under its business plan, StemExpress recruited and screened clinics that were most likely to perform abortions that could produce saleable tissue to researchers.[1] The company sought information about the number of abortions the clinics performed each week, the gestational age of fetuses scheduled to be aborted, the days the abortions were done, whether

[1] StemExpress Website Recruitment Form for Abortion Clinics, attachment 1.

digoxin[2] was used (which would taint the tissue and, thus, render the baby useless for obtaining tissue), and, if so, at what age it was used. Researchers ordered tissue using StemExpress' website. The firm initially had a drop-down menu that allowed researchers to obtain various types of tissue.[3] It later switched to another web-based system.

In order to harvest the tissue, StemExpress embedded tissue technicians inside the abortion clinics. Evidence uncovered by the Panel indicates females were recruited as tissue technicians to facilitate the consent process. The technicians' typical work day went as follows:

- At the beginning of the day, the tissue technician received an email from StemExpress including the day's orders for certain baby body parts and the gestation period, letting her know what she needed to harvest that day, and where she would be assigned.

- Once she arrived at the clinic, the tissue technician checked in with the Abortion Clinic Assistant Manager and informed the staff what she would procure that day.

- Then the technician reviewed the private medical files of the patients for that day to learn their names and the gestational ages of their babies. She recorded the gestations on the gestation tracking log provided by StemExpress.

- Next the technician met with the patients waiting to be prepped for their abortions, after receiving their names from clinic staff. Then she convinced them to consent to donate by saying that the donation will help cure diabetes, Parkinson's, and heart disease.[4]

- After an abortion, the technician collected the baby's remains and procured the body parts that were ordered, using her own supplies.[5] The technician then packed the tissues or body parts, and shipped them directly to the customer via a courier or FedEx.

- She received an hourly wage and a bonus for each tissue, illustrated in the attached pay rate and bonus chart.[6]

StemExpress' stunning revenue growth five years after its formation belies the notion that the firm was not operating for profit. In 2010, its revenue was $156,312; during 2011, that figure more than doubled to $380,000; a year later, in 2012, StemExpress' revenue nearly tripled to $910,000; by 2013, its revenue was $2.20 million; then in 2014, the revenue had once again more than doubled to $4.50 million. Based on its three-year revenue growth of 1,315.9%, *Inc. Magazine* named StemExpress one of the fastest-growing privately held companies in the U.S.[7]

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[2] Digoxin is a heart medication that sometimes is injected into the amniotic fluid or fetus to cause fetal demise before surgical or induction abortion. *See* Abortion in California: A Medical-Legal Resource, *available at* http://californiaabortionlaw.com/wp/?page_id=135.

[3] StemExpress Drop-Down Ordering Menu, attachment 2.

[4] BioMed IRB Informed Consent to Participate in a Clinical Research Study, Sponsor: StemExpress, LLC, attachment 3.

[5] *See* Standard Operating Procedure, Jan. 24, 2011, at 1 ("The clinic staff will identify donors"), attachment 4.

[6] StemExpress Embedded Technician Pay Rates and Bonuses, attachment 5.

[7] *The 500: Get to know the 500 fastest-growing privately held companies in America*, INC., Sept. 2014, at 137.

This revenue growth accompanied an aggressive marketing strategy directed toward abortion clinics. StemExpress distributed its brochure at a conference hosted by the National Abortion Federation (NAF). The brochure promised clinics they would be "[f]inancially profitable" if they allowed StemExpress to procure tissue from the clinics. The brochure also said "By partnering with StemExpress" the clinics will not only help research "but [they] will also be contributing to the fiscal growth of [their] own clinic[s]."[8]

When StemExpress was formed, billing records show the firm was procuring fetal tissue from four clinics. By the end of 2014, the firm had "relationships with more than 30 procurement sites across the country."[9] However, many of those procurement sites had multiple clinics, making the actual number nearly 100. In 2015, StemExpress tried to execute a contract with NAF that would have given the firm potential access to nearly 200 additional clinics. Its overall strategy was to provide on-demand body parts to researchers. In order to do that, the firm needed a ready supply of fetal tissue. The only way to achieve that was to dramatically increase the number of abortion clinics from which it would obtain fetal tissue.

StemExpress' Profit and Loss

Attached is a sample of a StemExpress invoice to a customer.[10] According to the accounting records obtained by the Panel, StemExpress paid approximately $55 for each fetal tissue sample or Product of Conception (POC) it obtained from abortion clinics and transferred it to researchers for up to $595 to $890 per tissue or body part. The following charts summarize payments StemExpress made to abortion providers to obtain fetal tissue and those it received from its customers for such tissue.

Payments from StemExpress to Abortion Providers

CLINIC	DATE	ITEM	COST
Camelback Family Planning	2015	[not specified]	$600
Camelback Family Planning	2015	[not specified]	$600
			Total: $1,200
Cedar River Clinic	2015	Amniotic	$100.00
Cedar River Clinic	2013	Blood Samples	$960.00
Cedar River Clinic	2014	Blood Samples	$2,600.00
Cedar River Clinic	2014	Femur	$125.00
Cedar River Clinic	2015	Femur	$75.00
Cedar River Clinic	2014	Fetal Indications	$7,250.00
Cedar River Clinic	2015	Fetal Indications	$4,250.00
Cedar River Clinic	2014	Gift Cards	$10,650.00

[8] StemExpress Brochure Distributed at NAF Conference, attachment 6 (key text highlighted).
[9] Complaint at para. 17, StemExpress, LLC v. Center for Medical Progress, No. BC-589145 (L.A. Super. Ct. filed Jul. 27, 2015).
[10] Sample StemExpress Invoice to Customer, attachment 7.

Cedar River Clinic	2015	Gift Cards	$10,250.00
Cedar River Clinic	2015	Hotel	$92.00
Cedar River Clinic	2014	Kit	$625.00
Cedar River Clinic	2015	Liver	$125.00
Cedar River Clinic	2014	Maternal Blood	$1,400.00
Cedar River Clinic	2014	Maternal Blood	$350.00
Cedar River Clinic	2014	Maternal Blood	$28,675.00
Cedar River Clinic	2015	Maternal Blood	$8,700.00
Cedar River Clinic	2014	Maternal Blood	$650.00
Cedar River Clinic	2015	Maternal Blood	$100.00
Cedar River Clinic	2014	Maternal Blood/Tissue Kit	$35,550.00
Cedar River Clinic	2015	Maternal Blood/Tissue Kit	$39,225.00
Cedar River Clinic	2015	Maternal Bood	$250.00
Cedar River Clinic	2015	Peripheral Blood	$6,350.00
Cedar River Clinic	2015	Rental Car	$167.98
Cedar River Clinic	2015	Thymus	$75.00
Cedar River Clinic	2014	Tissue	$225.00
Cedar River Clinic	2014	Tissue	$75.00
Cedar River Clinic	2015	Tissue Brain	$75.00
Cedar River Clinic	2015	Tissue Liver	$250.00
Cedar River Clinic	2014	Tissue Only	$500.00
Cedar River Clinic	2015	Tissue Only	$75.00
Cedar River Clinic	2015	Tissue Pancreas	$75.00
Cedar River Clinic	2015	Triscomy credit	$200.00
Cedar River Clinic	2014	Whole Blood	$12,850.00
Cedar River Clinic	2015	Whole Blood	$8,400.00
			Total: $181,319.98
Family Planning Specialist	2011	Blood Draws	$1,090.00
Family Planning Specialist	2012	Blood Draws	$5,325.00
Family Planning Specialist	2011	Specimen	$440.00
Family Planning Specialist	2012	Specimen	$6600
			Total: $13,455.00
Mar Monte	2010	Blood	$1,700
Mar Monte	2011	Blood	$33,153
Mar Monte	2012	Blood	$31,380
Mar Monte	2013	Blood	$16,080
Mar Monte	2014	Blood	$14,640
Mar Monte	2015	Blood	$3,190
Mar Monte	2010	POC	$1,210
Mar Monte	2011	POC	$15,235

Mar Monte	2012	POC	$43,245
Mar Monte	2013	POC	$24,140
Mar Monte	2014	POC	$25,990
Mar Monte	2015	POC	$13,355
			Total: $223,318.00
Presidential Women's Center	2014	Blood	$6,450.00
Presidential Women's Center	2015	Blood	$4,455.00
Presidential Women's Center	2014	Tissue Liver	$1,425.00
Presidential Women's Center	2015	Tissue Liver	$675.00
Presidential Women's Center	2015	Tissue Villi	$75.00
Presidential Women's Center	2015	Tissue Villi	$150.00
Presidential Women's Center	2015	Tissue Villi	$525.00
Presidential Women's Center	2014	Tissue Villi	$75.00
Presidential Women's Center	2015	Tissue Villi	$1,800
Presidential Women's Center	2015	Tissue Villi Twin a	$75.00
Presidential Women's Center	2015	Tissue Villi Twin b	$75.00
			Total: $15,780.00
Shasta Pacific	2012	Blood	$650.0
Shasta Pacific	2013	Blood	$4,470.00
Shasta Pacific	2014	Blood	$2,530.00
Shasta Pacific	2015	Blood	$100.00
Shasta Pacific	2012	POC	$1,870.00
Shasta Pacific	2013	POC	$3,960.00
Shasta Pacific	2014	POC	$6,160.00
Shasta Pacific	2015	POC	$715.00
			Total: $20,455.00
			GRAND TOTAL: $455,527.98

Payments from Customers to StemExpress for Fetal Tissue

CUSTOMER	YEAR	TOTAL PAYMENTS
All Cells	2011	$4,040
Columbia University	2011	$540
Colorado State University	2011	$2,700
Dartmouth	2011	$3,240
Drexel University	2011	$3,510
Johns Hopkins	2011	$1,950
Ohio State University	2011	$235
Stanford University	2011	$28,650
University of California – Los Angeles	2011	$3,920
University of Connecticut	2011	$930
University of Massachusetts Medical School	2011	$43,115
Vanderbilt University Medical Center	2011	$2,700
Yale College of Medicine	2011	$390
Zyagen	2011	$3,910
All Cells	2012	$5,680
Baylor College of Medicine	2012	$2,500
Columbia University	2012	$2,925
Colorado State University	2012	$1,220
Dartmouth	2012	$4,160
George Washington University	2012	$435
Johns Hopkins	2012	$1,680
Massachusetts General Hospital	2012	$3,000
Stanford University	2012	$32,385
University of California – Los Angeles	2012	$9,370
University of Connecticut	2012	$1,110
University of Massachusetts Medical School	2012	$32,290
Vanderbilt University Medical Center	2012	$7,460
Yale College of Medicine	2012	$6,825
University of North Carolina	2012	$720
University of Illinois at Chicago	2012	$250
All Cells	2013	$3,920
Baylor College of Medicine	2013	$1,000
City of Hope	2013	$350
Columbia University	2013	$750
Colorado State University	2013	$2,250
Dartmouth	2013	$500
Ganogen, Inc.	2013	$6,825
Harvard	2013	$6,680
Massachusetts General Hospital	2013	$7,125
Rockefeller University	2013	$250

Stanford University	2013	$16,065
Thomas Jefferson University	2013	$500
University of California – Los Angeles	2013	$9,000
University of Connecticut	2013	$500
University of Illinois at Chicago	2013	$16,750
University of North Carolina	2013	$1,750
University of Pennsylvania	2013	$2,750
Vanderbilt University Medical Center	2013	$3,000
City of Hope	2014	$595
Ganogen, Inc.	2014	$795
Medical College of Wisconsin	2014	$2,380
Stanford University	2014	$42,535
University of Massachusetts Medical School	2014	$2,380
Vanderbilt University Medical Center	2014	$595
Children's Hospital of Philadelphia	2015	$1,190
City of Hope	2015	$595
Neurona Therapeutics	2015	$1,190
Stanford University	2015	$20,670
University of Massachusetts Medical School	2015	$595
Zyagen, Inc.	2015	$3,578

A more detailed breakdown of these tissue payments is attached hereto.[11]

Attorneys for StemExpress created several cost estimates that purport to show that StemExpress loses money each time it procures a fetal tissue sample and ships it to a customer, but the Panel's staff conducted an analysis of those estimates. A comparison of invoices, attorney-created accounting documents purporting to state costs, and productions from multiple StemExpress customers shows that the firm likely made a profit when procuring and transferring fetal tissue. Attached hereto[12] is a component of the Panel's analysis, which shows StemExpress overstated some of its labor costs and claimed as expenses shipping, supplies, and infectious disease screenings. These were costs charged to researchers.

Violation of Applicable Laws

Under 42 U.S.C. § 289g-2, it is unlawful for any person to "knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce."[13] The term "'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[14] Anyone who violates this law is subject to a fine "not less than

[11] List of StemExpress Fetal Tissue Sales by Customer, 2011-2015, attachment 8.
[12] Select Panel Analysis of StemExpress Statement of Costs, attachment 9.
[13] 42 U.S.C. § 289g-2(a).
[14] 42 U.S.C. § 289g-2(e)(3).

twice the amount of the valuable consideration received" and/or imprisonment for up to ten years.[15]

California state law includes a nearly identical prohibition. Under Cal. Health & Safety Code § 125320(a), a "person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes." The California statute's definition of "valuable consideration" is virtually identical to that of the federal statute.[16] Similar provisions in the California Penal Code § 367f(a) prohibit the acquisition, sale, or transfer of "any human organ, for purposes of transplantation, for valuable consideration," subject to a fine of up to $50,000 and imprisonment for up to five years.[17]

The foregoing analysis establishes with a high level of probability that StemExpress and the clinics and research institutions with which it contracted routinely violated 42 U.S.C. § 289g-2 and Cal. Health & Safety Code § 125320(a). This is established generally by the company's aggressive growth strategy, which explicitly included the goal of generating profit, and specifically by the transactions involving the transfer of fetal tissue to and from numerous entities for consideration that exceeded statutorily allowable costs. To the extent any of these transactions occurred for purposes of transplantation, StemExpress and any business partners so involved would additionally be in violation of California Penal Code § 367f(a).

The Panel's investigation additionally revealed indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. During that time, the aforementioned clinics, which are "covered entities" under HIPAA, permitted employees of StemExpress, a noncovered entity, to enter their clinics and procure human fetal tissue from aborted infants, obtain PHI about their patients, interact with patients, and seek and obtain patient consent for tissue donation. StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefited both sides of the respective contracts. StemExpress employees were routinely handed a patient's medical chart by her healthcare provider, in blatant violation of the HIPAA privacy rule.

These clinics and StemExpress violated the HIPAA privacy rule because: (a) the disclosures of patients' PHI made by the abortion clinics and received by StemExpress were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (b) the consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (c) the disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (d) StemExpress is not a business associate of the abortion clinics under HIPAA.

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[15] 42 U.S.C. § 289g-2(d).

[16] Such consideration "does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part." Cal. Health & Safety Code § 125320(b).

[17] Cal. Penal Code §§ 367f(a), (g).

The abortion clinics could have directly consented their patients for tissue donation and entered an agreement with StemExpress to provide a limited data set regarding the patients they were seeing on a particular day.[18] Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients. These disclosures made by the abortion clinics to StemExpress were intentional and purposeful.[19] The Panel made a referral of each of these entities to the Department of Health and Human Services, and requested a swift and full investigation by the HHS Office of Civil Rights. A copy of this referral detailing the foregoing facts is attached hereto.[20]

Also relevant are the federal regulations governing consent prior to the acquisition of fetal tissue. Under 45 C.F.R. § 46, the Department of Health and Human Services requires investigators to obtain informed consent from each human being used as a research subject.[21] The rule lists several criteria for Institutional Review Board ("IRB") approval, including the requirement that researchers obtain the informed consent from their research subjects. As was demonstrated in the Panel's referral to the Secretary of Health and Human Services, attached hereto,[22] StemExpress' procurement of fetal tissue from abortion clinics and transfer thereof to research customers violated 45 C.F.R. § 46: The company devised the appearance of compliance with the regulations while fraudulently using invalid consent forms and misleading customers to believe it had a valid IRB approval.

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov, or Mary Harned, at (202) 480-7160, Mary.Harned@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

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[18] *See* 45 C.F.R. § 164.514(e).
[19] *See* 45 C.F.R. § 164.502(a)(1)(iii).
[20] Letter from Rep. Marsha Blackburn, Chair, Select Investigative Panel, to Jocelyn Samuels, Director, Centralized Case Management Operations, Department of Health and Human Services, June 1, 2016, attachment 10.
[21] 45 C.F.R. § 46.116.
[22] Letter from Rep. Marsha Blackburn, Chair, Select Investigative Panel, to Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, June 1, 2016, attachment 11.

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

The Honorable Vern Pierson
El Dorado County District Attorney

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

VIA EMAIL

June 1, 2016

Ms. Jocelyn Samuels, Director
Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHS Bldg.
Washington, D.C. 20201

Dear Director Samuels:

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the business practices of businesses who procure and resell fetal tissue.

The Panel's investigation uncovered a series of business contracts between StemExpress,[1] a tissue procurement business ("TPB"), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

These contracts produced a regime of cooperation between StemExpress and each clinic. In particular: (1) the day before scheduled abortions, StemExpress received a fax from a clinic with information about the abortions scheduled for the next day; (2) StemExpress employees were granted access to the medical files of individual patients; (3) The clinic's medical employees (doctors and nurses) directed the StemExpress employees to particular patients who were "good candidates" for fetal tissue donations; (4) the StemExpress employees had access to the "patient terminal" inside the abortion clinic; and (5) the StemExpress employees were permitted by the abortion clinic to interview the patients about personal information, including their dates of birth.

[1] StemExpress and Stem-Ex are the same company.

In particular, the Panel's investigation has uncovered information indicating that StemExpress and Planned Parenthood Mar Monte ("PPMM"), Planned Parenthood Shasta Pacific ("PPSP") and Family Planning Specialists Medical Group ("FPS") (hereinafter "the abortion clinics") committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") privacy rule from about 2010 to 2015. **These violations occurred when the abortion clinics disclosed patients' *individually identifiable health information* to StemExpress to facilitate the TPB'S efforts to procure human fetal tissue for resale.** This complaint is against each of these entities, and we request a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services.

In addition to this letter, we are submitting a referral to the HHS Office for Human Research Protections indicating that StemExpress violated 45 CFR 46 by using invalid consent forms and failing to have valid Institutional Review Board ("IRB") approval.[2]

I. BACKGROUND

The abortion clinics are "covered entities" under HIPAA, while StemExpress is not.[3] StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."[4]

From about 2010 to 2015, the abortion clinics permitted StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain *individually identifiable health information*, or *protected health information* ("PHI") about their patients; interact with patients; and seek and obtain patient consent for tissue donation.[5] StemExpress embedded tissue procurement technicians inside the abortion clinics whose **work sequence** followed a daily routine:

1. A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue.[6]

2. The abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.[7]

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[2] *See* Attachment A.
[3] *See* 45 CFR Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) *See also* OCR Privacy Brief, Summary of the HIPAA Privacy Rule, *available at* http://www.hhs.gov/sites/default/files/privacysummary.pdf (last visited May 5, 2016) (used as reference throughout this complaint).
[4] Stemexpress, About Us, *available at* http://stemexpress.com/about/ (last visited Apr. 29, 2016).
[5] *See* Attachment B: Clinic Procedures & Policies.
[6] *See* Attachment C: Researcher Procurement Record.
[7] *See* Attachment D: Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.

3. The day the abortion procedures were scheduled, StemExpress posted the order on a website "task board" (order page) to be accessed by their procurement technician or communicated the order to the tissue technician via email.[8]

4. The StemExpress procurement technician informed the clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic provided the medical files, including PHI, for the patients with abortions scheduled for that day.[9]

5. The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. The procurement technician was also permitted to interview patients and obtain their PHI.[10]

6. StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page.[11]

7. StemExpress paid the abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for sale to the researcher.[12]

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.[13]

II. THE HIPAA PRIVACY RULE

The HIPAA privacy rule ("Privacy Rule") protects all *individually identifiable health information* held or transmitted by a covered entity or its business associate, and calls this information *protected health information* ("PHI").[14] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security Number), and includes demographic data relating to: an individual's past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.[15]

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[8] *See* Attachment E: Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Attachment F: Navigating The Task Board.
[9] *See* Attachment G: StemExpress Emails.
[10] *See* Attachment B, *supra*: Clinic Procedures and Policies and Attachment H: Consenting Patients.
[11] *See* Attachment I: Procurement Technician Compensation Policy for Tissue and Blood Procurement.
[12] See Attachment J: StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439.
[13] *See* Attachment K: Standard Operating Procedure.
[14] 45 C.F.R. § 160.103.
[15] 45 C.F.R. § 160.103.

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,[16] or as the individual or their representative authorizes in writing (see discussion below). HHS may impose civil money penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses, and any person who knowingly obtains, PHI in violation of the Privacy Rule can face criminal fines or imprisonment.[17]

III. THE CONTRACTS BETWEEN STEMEXPRESS AND THE ABORTION CLINICS

Particular language, contained within the four corners of the written contracts between StemExpress and the abortion clinics raises serious concerns that the parties violated the Privacy Rule.

The written contracts between StemExpress and the abortion clinics contain the following language:

> [a]ny information obtained from [the abortion clinics] patients' charts shall be privileged, and [Stem-Ex / StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex / StemExpress] will not receive any information concerning identity of donors **except as necessary to obtain patients' consent** for use of POCs and maternal bloods (emphasis added).[18]

This admission, on the face of the contracts, that the abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI **prior to obtaining patients' consent to donate fetal tissue *or* patients' authorization to view their PHI.**

IV. VIOLATIONS OF THE HIPAA PRIVACY RULE BY STEMEXPRESS AND THE ABORTION CLINICS

This complaint argues that the agreements between StemExpress and the abortion clinics, on their face and in practice, are fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" **cannot trump a law prohibiting the abortion clinics from permitting these disclosures in the first place.** As discussed below, the abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (A) The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were

[16] 45 C.F.R. §164.502(a).
[17] Pub. L. 104-191; 42 U.S.C. §§ 1320d-5 – 1320d-6.
[18] *See* Attachments L, M, and N.

neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (B) The consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (C) The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (D) StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A. The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research.

The disclosures of PHI that the abortion clinics made to StemExpress are neither required[19] nor permitted[20] by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.[21] **Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers.**

1. Cadaveric organ, eye or tissue transplantation

Importantly, the disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act," 42 U.S.C. 274e(c)(1), the abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. **Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for *research,* which is not covered by the cadaveric organ, eye or tissue exception.**[22]

2. Research

Further, the disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board ("IRB") for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.[23]

3. Violations Preceding "Consent"

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[19] 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).
[20] *See* 45 C.F.R. § 164.502(a)(1).
[21] *See* 45 C.F.R. § 164.506(c).
[22] *See* 45 C.F.R. § 164.512(h).
[23] 45 C.F.R. § 164.512(i).

Because StemExpress employees actually sought consent for tissue donation from patients, the abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past and present medical treatment, and more. **Each time that an abortion clinic employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.**

No evidence suggests the abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set[24] regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the abortion clinics to StemExpress were inarguably direct and intentional—not incidental.[25] StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. The consent for fetal tissue donation obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI.

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule.

The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.[26] Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.[27]

Neither the consent form provided by StemExpress ("SE form") nor the consent form provided by Planned Parenthood ("PP form") to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.[28] The statement in the SE form that a patient's "health information will be protected at all times" is ironic given that StemExpress's possession of the patient's PHI already placed the abortion clinics and StemExpress in violation of the HIPAA privacy rule.

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[24] *See* 45 C.F.R. § 164.514(e).
[25] *See* 45 C.F.R. §§ 164.502(a)(1)(iii).
[26] 45 C.F.R. § 164.508.
[27] 45 C.F.R. § 164.508(c).
[28] *See* Attachments O: StemExpress Consent Form and P: Planned Parenthood Consent Form.

The SE form also stated that "[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier."[29]

Like the privacy provision in the contracts between Stem Express and the abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The SE form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The SE form did not state who will disclose or use the patient's PHI. It also did not state when the patient's authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The PP form, purportedly used to obtain patient consent for human fetal tissue donation at PPMM and PPSP,[30] was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient's PHI to researchers or others; or the patient's right to revoke her authorization in writing.

C. The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants.

The abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the "minimum necessary" PHI to facilitate the procurement of human fetal tissue from aborted infants.[31] StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients' consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by the abortion clinics.

As addressed above, the abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue that would later be sold by StemExpress to researchers at a huge mark-up.

D. StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting,

[29] Attachment O, *supra*.
[30] Attachment P, *supra*.
[31] 45 C.F.R. §§ 164.502(b) and164.514(d).

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

VIA EMAIL

June 1, 2016

Mr. Jerry Menikoff
Director, Office for Human Research Protections
Department of Health and Human Services
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear Director Menikoff:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered the panel to conduct a full and complete investigation regarding the medical practice of abortion providers and the business practices of firms that procure and resell fetal tissue.

During the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC ("StemExpress"), a for-profit firm which procures fetal tissue from abortion clinics and transfers it to research customers, violated 45 CFR 46 by using the appearance of compliance with the regulations, while fraudulently using invalid consent forms, and misleading customers to believe it had a valid Institutional Review Board ("IRB") approval.

In addition to this letter, I have included as Attachment A another referral to the U.S. Department of Health and Human Services, Centralized Case Management Operations.

consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.[32]

Clearly, StemExpress did not perform one of these services for the abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the abortion clinics' patients.

CONCLUSION

We appreciate your swift attention to the serious and systematic violations of the HIPAA privacy rule committed by StemExpress, Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, and Family Planning Specialists Medical Group. If you have any questions about this request, please contact Mary Harned, Investigative Counsel at (202) 480-7160, or by email at Mary.Harned@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

[32] 45 C.F.R. § 160.103.

Background

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Through its corporate existence, StemExpress' activities were obtaining contractual relationships with abortions clinics for the purpose of embedding a StemExpress company employee inside the clinic. The employees had access to confidential patient medical records, which they used to obtain consent and procure fetal tissue. StemExpress then resold that tissue to researchers. StemExpress pays the abortion clinic a per-specimen fee and then marks up the specimen four to six hundred percent for sale to a research institution.

Stem Express' tissue procurement technicians embedded inside the abortion clinics had the following daily **work sequence**:

- A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue. (See Attachment B, "Researcher Procurement Record.").

- When it first began operations, the abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic. (See Attachment C, "Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.").

- The day the abortion procedures were scheduled, StemExpress emailed the procurement schedule to its tissue technicians. (See Attachment D, "Updated Task Assignment: Procurement Schedule Wednesday, 3/30/13.").

- Emails produced by StemExpress demonstrate that its employees knew beforehand protected health information, including gestation periods of fetuses. For example: On January 6, 2015, a StemExpress employee emailed a customer that: "There are no patients that qualify for your request today. You will be on the schedule again for tomorrow, but the cases are all low gestation." On January 14, 2015, at 12:40 p.m., a StemExpress employee emailed a researcher: "Unfortunately, there is nothing within your gestational requirements today. There will be some potentials tomorrow, would you like to be on the schedule?" Hours later, the customer emailed: "Yes, please put me on the schedule for tomorrow." On April 14, 2015, a StemExpress employee emailed a researcher: We have a trisomy patient scheduled for this week and could try to procure a brain sample for you . . . ." (See Attachement E, "Emails.").

- As the firm became more computerized, tissue procurement technicians logged into a Website. (See Attachement F, "Navigating The Task Board.").

- The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. (See Attachment G, "Clinic Procedures and Policies.").

- StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page. (See Attachment H, "Procurement Technician Compensation Policy for Tissue and Blood Procurement.").

- StemExpress paid the abortion clinic a per tissue fee and then marked up the tissue four to six hundred percent for sale to the researcher. (See Attachment I, "StemExpress Services Agreement with Planned Parenthood Shasta Pacific," "StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties;" and Attachment J, "Purchase Order No. 60856806," "Purchase Order No. 3000014694," "Purchase Order No. 60836838," "Purchase Order No. 60858758," and "StemExpress Invoice # 1439.").

Documents produced to the Panel prove that StemExpress' tissue procurement technicians knew in advance of the abortion schedules, the clinics assisted them with obtaining consent, and the entire work flow was designed to maximize the firm's profits. For example instructions to the tissue procurement technicians (See Attachment K, "Standard Operating Procedure") states:

> The day before [the abortion] surgery: Check WebOffice [apparently an earlier version of the Task Board] for research requests; Determine your location for the next day; Call the clinic to verify how many surgeries are scheduled . . . .
>
> The clinic staff will identify donors. It is the procurement technician's responsibility to retrieve the tissue and package it appropriately for the given researcher. It is also the procurement technician's responsibility to update WebOffice so everyone is aware what tissue has been obtained and for whom.
>
> . . . On the day of the surgery, the following steps are taken to procure tissue from POC [Products Of Conception; i.e., fetal tissue] . . . Print a copy of the day's Procurement Schedule. Following along the chart flow so you know what gestations to expect.
>
> . . . Keep track of [the] time [of procurement], gestation [age], fetal foot size or sono[gram] report and date.
>
> . . . If you have an excellent sample with no researcher listed on today's schedule, please contact [redacted] Stem Express' President and CEO] immediately, and

> they will work to call researchers who may be interested even though they are not currently scheduled.

The work sequence, when combined with the supporting documents reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' protected health information ("PHI"). Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.

Informed Consent

HHS requires investigators to obtain informed consent from each human being used as a research subject.[1] The "basic elements of informed consent" include the following information:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; . . . [and]
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research . . .[2]

Documents produced by StemExpress to the Select Panel indicate the firm did not follow those regulations. One of those documents is Attachment L, "A Form for Informed Consent To Participate In A Clinical Research Study, involving the donation of aborted pregnancy tissue for medical research, education, or treatment." It states:

> Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and more. . . .
>
> The benefits of consenting to donation today include furthering medical research in finding cures for disease like diabetes, leukemia, lymphoma, Parkinson's disease and more.

The Panel notes that the StemExpress consent form specifically does not conform to the General requirements for informed consent mandated under 45 CFR 46 §116. Witnesses at a recent Select Panel hearing agreed that forms similar to the one StemExpress used apparently do not conform to the HHS regulations on informed consent.[3]

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[1] 45 CFR 46 §116.
[2] *Id.*
[3] See generally House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016.

Coercion or Undue Influence

The requirements for informed consent further state that investigators "shall seek such consent only under circumstances that provide the prospective subject with . . . sufficient opportunity to consider whether or not to participate and that **minimize the possibility of coercion or undue influence.**" [emphasis added].[4]

The regulations further state: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as . . . pregnant women . . . additional safeguards" are included.[5] Documents produced by StemExpress indicate the firm only obtained fetal tissue from women who had undergone abortions at abortion clinics, and the company's employees were the ones obtaining consent. It is unclear whether such consent occurred before or after the procedures was conducted.

Additional documents produced by StemExpress demonstrate that tissue procurement technicians engaged in real-time email correspondence with researchers while abortions were taking place - presumably before they obtained informed consent to procure fetal tissue - and yet StemExpress employees already were promising to deliver products of conception. (See Attachment M, "Emails regarding PO # 60858758."). The emails reveal that a customer had placed an order for a skull and limbs.

On January 22, 2015, at 12:26 p.m., the customer emailed a StemExpress employee stating: "Just wanted to check in and see if there are any cases within our gestation range for today? Need to book some time on the equipment if so." Within minutes, at 12:30:11 p.m., the StemExpress employee replied: "There is one case currently in the room, I will let you know how the limbs and calvarium [skull] look to see if you are able to take them in about fifteen minutes." Less than two minutes later, the customer wrote: "Great thank you so much." At 1:20:32 p.m., the StemExpress employee informed the customer: "The calvarium is mostly intact, with a tear up the back of the suture line, but all pieces look to be there. The limbs, one upper and one lower, are totally intact, with one upper broken at the humerus, and one lower broken right above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply." Approximately five minutes later, the customer replied: "That sounds great we would like both of them. Please send them our way. Thanks again . . ." The StemExpress employee responded: "Limbs and calvarium will be there between 3:30 and 4:00."

The fact that StemExpress was attempting to interest a customer in fetal body parts **before an abortion had taken place** raises serious concerns that there may have been coercion or undue influence upon the patient to consent to procurement. Both Members and witnesses at our recent hearing raised the same question.[6]

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[4] 45 CFR 46 §110(4) and (7)(b).
[5] *Id.*
[6] See generally House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016.

IRB

Documents produced by StemExpress violated 45 CFR 46 by misleading customers into believing it had a valid IRB approval. StemExpress obtained approval for its "study" from BioMed IRB (Seen Attachment N, "Informed Consent To Participate In A Clinical Research Study," and "BioMed IRB Continual Approval Notification.").

In fact, one of StemExpress' marketing materials advertises the firm provides clinics with "IRB Certified Consents," and that "Our IRB approved **protocols** and **consents** protect you as well as donor's privacy in accordance with HIPAA guidelines." (Attachment O, StemExpress marketing brochure.).

At our recent hearing, Dr. G. Kevin Donovan, the senior clinical scholar at the Kennedy Institute of Ethics at Georgetown University, and director of the Pellegrino Center for Clinical Bioethics at Georgetown University, said actions such as those undertaken by StemExpress "would never pass muster for an IRB."[7] Yet StemExpress purportedly had the approval of an IRB.

HHS regulations require IRBs to "prepare and maintain adequate documentation" of its activities, including:

> (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
>
> (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
>
> (3) Records of continuing review activities.
>
> (4) Copies of all correspondence between the IRB and the investigators . . . .[8]

On March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of Title 45 Code of Federal Regulations Part 46, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval.[9]

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[7] House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016, at. P. 91.
[8] 45 CFR § 46.115 (a).
[9] House of Representatives, Select Investigative Panel on Infant Lives, Subpoena to Biomedical Research Institute of America, Mar. 29, 2016.

BioMed IRB's executive director informed the Panel on April 4, 2016 that, in regards to those records, "there are none."[10] This apparently is a direct violation of 45 CFR 46.

While regulation of IRBs does not fall under the auspices of OHRP, it may interest you to know that, in March of 2012, the Food and Drug Administration ("FDA") issued a warning letter to BioMed IRB, citing: A failure to fulfill membership requirements; failure to prepare, maintain, and follow adequate written procedures for conducting the review of research, including initial and continuing review; and keeping minutes that were not sufficient to show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution. As a result, the FDA ruled it "will withhold approval of all new studies subject to 21 CFR Part 56 and reviewed by the IRB; and [n]o new subjects are to be enrolled in any ongoing studies subject to 21 CFR Part 56 and approved by the IRB."[11] That ban was lifted in January 2013.[12]

Given the facts outlined above, and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated 45 CFR 46, and, if OHRP agrees that such violations occurred, to take all appropriate actions.

Respectfully yours,

Marsha Blackburn
Chair, Select Investigative Panel

cc: Rep. Jan Schakowsky
Ranking Member

[10] Email from Fred Fox, Executive Director, Biomedical Research Institute of America, to Select Panel staff, Apr. 4, 2016.
[11] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Mar. 29, 2012.
[12] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Jan. 16, 2013.

Attachment A:

Letter to Ms. Jocelyn Samuels,

Director, Centralized Case Management Operations

U.S. Department of Health and Human Services

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225–2927

Minority (202) 225–3641

VIA EMAIL

June 1, 2016

Ms. Jocelyn Samuels, Director
Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHS Bldg.
Washington, D.C. 20201

Dear Director Samuels:

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the business practices of businesses who procure and resell fetal tissue.

The Panel's investigation uncovered a series of business contracts between StemExpress,[1] a tissue procurement business ("TPB"), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

These contracts produced a regime of cooperation between StemExpress and each clinic. In particular: (1) the day before scheduled abortions, StemExpress received a fax from a clinic with information about the abortions scheduled for the next day; (2) StemExpress employees were granted access to the medical files of individual patients; (3) The clinic's medical employees (doctors and nurses) directed the StemExpress employees to particular patients who were "good candidates" for fetal tissue donations; (4) the StemExpress employees had access to the "patient terminal" inside the abortion clinic; and (5) the StemExpress employees were permitted by the abortion clinic to interview the patients about personal information, including their dates of birth.

[1] StemExpress and Stem-Ex are the same company.

In particular, the Panel's investigation has uncovered information indicating that StemExpress and Planned Parenthood Mar Monte ("PPMM"), Planned Parenthood Shasta Pacific ("PPSP") and Family Planning Specialists Medical Group ("FPS") (hereinafter "the abortion clinics") committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") privacy rule from about 2010 to 2015. **These violations occurred when the abortion clinics disclosed patients' *individually identifiable health information* to StemExpress to facilitate the TPB'S efforts to procure human fetal tissue for resale.** This complaint is against each of these entities, and we request a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services.

In addition to this letter, we are submitting a referral to the HHS Office for Human Research Protections indicating that StemExpress violated 45 CFR 46 by using invalid consent forms and failing to have valid Institutional Review Board ("IRB") approval.[2]

I. BACKGROUND

The abortion clinics are "covered entities" under HIPAA, while StemExpress is not.[3] StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."[4]

From about 2010 to 2015, the abortion clinics permitted StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain *individually identifiable health information*, or *protected health information* ("PHI") about their patients; interact with patients; and seek and obtain patient consent for tissue donation.[5] StemExpress embedded tissue procurement technicians inside the abortion clinics whose **work sequence** followed a daily routine:

1. A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue.[6]

2. The abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.[7]

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[2] *See* Attachment A.
[3] *See* 45 CFR Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) *See also* OCR Privacy Brief, Summary of the HIPAA Privacy Rule, *available at* http://www.hhs.gov/sites/default/files/privacysummary.pdf (last visited May 5, 2016) (used as reference throughout this complaint).
[4] Stemexpress, About Us, *available at* http://stemexpress.com/about/ (last visited Apr. 29, 2016).
[5] *See* Attachment B: Clinic Procedures & Policies.
[6] *See* Attachment C: Researcher Procurement Record.
[7] *See* Attachment D: Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.

3. The day the abortion procedures were scheduled, StemExpress posted the order on a website "task board" (order page) to be accessed by their procurement technician or communicated the order to the tissue technician via email.[8]

4. The StemExpress procurement technician informed the clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic provided the medical files, including PHI, for the patients with abortions scheduled for that day.[9]

5. The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. The procurement technician was also permitted to interview patients and obtain their PHI.[10]

6. StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page.[11]

7. StemExpress paid the abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for sale to the researcher.[12]

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.[13]

II. THE HIPAA PRIVACY RULE

The HIPAA privacy rule ("Privacy Rule") protects all *individually identifiable health information* held or transmitted by a covered entity or its business associate, and calls this information *protected health information* ("PHI").[14] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security Number), and includes demographic data relating to: an individual's past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.[15]

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[8] *See* Attachment E: Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Attachment F: Navigating The Task Board.
[9] *See* Attachment G: StemExpress Emails.
[10] *See* Attachment B, *supra*: Clinic Procedures and Policies and Attachment H: Consenting Patients.
[11] *See* Attachment I: Procurement Technician Compensation Policy for Tissue and Blood Procurement.
[12] See Attachment J: StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439.
[13] *See* Attachment K: Standard Operating Procedure.
[14] 45 C.F.R. § 160.103.
[15] 45 C.F.R. § 160.103.

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,[16] or as the individual or their representative authorizes in writing (see discussion below). HHS may impose civil money penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses, and any person who knowingly obtains, PHI in violation of the Privacy Rule can face criminal fines or imprisonment.[17]

III. THE CONTRACTS BETWEEN STEMEXPRESS AND THE ABORTION CLINICS

Particular language, contained within the four corners of the written contracts between StemExpress and the abortion clinics raises serious concerns that the parties violated the Privacy Rule.

The written contracts between StemExpress and the abortion clinics contain the following language:

> [a]ny information obtained from [the abortion clinics] patients' charts shall be privileged, and [Stem-Ex / StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex / StemExpress] will not receive any information concerning identity of donors **except as necessary to obtain patients' consent** for use of POCs and maternal bloods (emphasis added).[18]

This admission, on the face of the contracts, that the abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI **prior to obtaining patients' consent to donate fetal tissue *or* patients' authorization to view their PHI.**

IV. VIOLATIONS OF THE HIPAA PRIVACY RULE BY STEMEXPRESS AND THE ABORTION CLINICS

This complaint argues that the agreements between StemExpress and the abortion clinics, on their face and in practice, are fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" **cannot trump a law prohibiting the abortion clinics from permitting these disclosures in the first place.** As discussed below, the abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (A) The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were

[16] 45 C.F.R. §164.502(a).
[17] Pub. L. 104-191; 42 U.S.C. §§ 1320d-5 – 1320d-6.
[18] *See* Attachments L, M, and N.

neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (B) The consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (C) The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (D) StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A. The disclosures of patients' PHI made by the abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research.

The disclosures of PHI that the abortion clinics made to StemExpress are neither required[19] nor permitted[20] by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.[21] **Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers.**

1. Cadaveric organ, eye or tissue transplantation

Importantly, the disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act," 42 U.S.C. 274e(c)(1), the abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. **Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for *research*, which is not covered by the cadaveric organ, eye or tissue exception.**[22]

2. Research

Further, the disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board ("IRB") for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.[23]

3. Violations Preceding "Consent"

[19] 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).
[20] *See* 45 C.F.R. § 164.502(a)(1).
[21] *See* 45 C.F.R. § 164.506(c).
[22] *See* 45 C.F.R. § 164.512(h).
[23] 45 C.F.R. § 164.512(i).

Because StemExpress employees actually sought consent for tissue donation from patients, the abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past and present medical treatment, and more. **Each time that an abortion clinic employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.**

No evidence suggests the abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set[24] regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the abortion clinics to StemExpress were inarguably direct and intentional—not incidental.[25] StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. The consent for fetal tissue donation obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI.

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule.

The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.[26] Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.[27]

Neither the consent form provided by StemExpress ("SE form") nor the consent form provided by Planned Parenthood ("PP form") to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.[28] The statement in the SE form that a patient's "health information will be protected at all times" is ironic given that StemExpress's possession of the patient's PHI already placed the abortion clinics and StemExpress in violation of the HIPAA privacy rule.

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[24] *See* 45 C.F.R. § 164.514(e).
[25] *See* 45 C.F.R. §§ 164.502(a)(1)(iii).
[26] 45 C.F.R. § 164.508.
[27] 45 C.F.R. § 164.508(c).
[28] *See* Attachments O: StemExpress Consent Form and P: Planned Parenthood Consent Form.

The SE form also stated that "[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier."[29]

Like the privacy provision in the contracts between Stem Express and the abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The SE form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The SE form did not state who will disclose or use the patient's PHI. It also did not state when the patient's authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The PP form, purportedly used to obtain patient consent for human fetal tissue donation at PPMM and PPSP,[30] was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient's PHI to researchers or others; or the patient's right to revoke her authorization in writing.

C. The disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants.

The abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the "minimum necessary" PHI to facilitate the procurement of human fetal tissue from aborted infants.[31] StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients' consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by the abortion clinics.

As addressed above, the abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue that would later be sold by StemExpress to researchers at a huge mark-up.

D. StemExpress is not a *Business Associate* of the abortion clinics under HIPAA.

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting,

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[29] Attachment O, *supra*.
[30] Attachment P, *supra*.
[31] 45 C.F.R. §§ 164.502(b) and164.514(d).

consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.[32]

Clearly, StemExpress did not perform one of these services for the abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the abortion clinics' patients.

CONCLUSION

We appreciate your swift attention to the serious and systematic violations of the HIPAA privacy rule committed by StemExpress, Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, and Family Planning Specialists Medical Group. If you have any questions about this request, please contact Mary Harned, Investigative Counsel at (202) 480-7160, or by email at Mary.Harned@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

[32] 45 C.F.R. § 160.103.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 2, 2016

VIA EMAIL

The Honorable Leslie Carol Rutledge
Attorney General
State of Arkansas
323 Center Street, Suite 200
Little Rock AR 72201

Dear Attorney General Rutledge:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC ("StemExpress"), a firm that procures(d) fetal tissue from abortion clinics and transfers it to research customers,[1] violated state law, including but not limited to the Arkansas Anatomical Gift Act ("A.C.A.") § 120-17-802 (2)(c), which forbid the transfer of fetal tissue for valuable consideration.

Among the abortion clinics from which StemExpress sought to procure fetal tissue was Little Rock Family Planning Services,[2] which is located at [redacted].[3]

The A.C.A. makes it a five-year felony if a person "for valuable consideration, knowingly purchases or sells a part for transplantation or therapy if removal of a part from an individual is

[1] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Interim Update to the U.S. House of Representatives, Jul. 14, 2016, https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20160714Interim_Update.pdf.
[2] *See* Letter from [redacted], counsel for Little Rock Family Planning Services, to Matthew Tallmer, Investigator, Select Investigative Panel on Infant Lives [sic], Oct. 10, 2016.
[3] Little Rock Family Planning Services Website, https://lrfps.com/, last accessed Oct. 11, 2016.

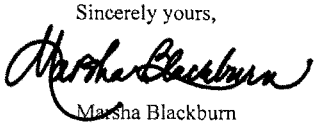
intended to occur after the individual's death . . ."[4] The A.C.A. goes on to state that an individual "may charge a reasonable amount for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of a part."[5]

Another section of the A.C.A., however, states that: "A person shall not buy, sell, give, exchange, or barter or offer to buy, sell, give, exchange, or barter any fetus born dead as a result of a legal abortion or any organ, member, or tissue of fetal material resulting from a legal abortion."[6]

In a letter to the Panel, the counsel for Little Rock Family Planning Services ("LRFPS") wrote: "In 2015, LRFPS entered into a contract with StemExpress . . . . In June 2015, LRFPS collected two fetal tissue samples pursuant to appropriate written patient consents. Both samples were sent to StemExpress."[7]

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chair
Select Investigative Panel

Attachment

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

[4] A.C.A. § 20-17-1216 (a).
[5] A.C.A. § 20-17-1216 (b).
[6] A.C.A. § 20-17-802(c)
[7] *Supra* note 2.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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Majority (202) 225–2927
Minority (202) 225–3641

November 2, 2016

VIA EMAIL

The Honorable Tony Rackauckas
District Attorney, County of Orange
401 Civic Center Drive West
Santa Ana, California 92701

Dear District Attorney Rackauckas:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents that indicate DV Biologics, LLC ("DaVinci"), DaVinci Biosciences, LLC ("DVB"), two related firms that procured fetal tissue from a Planned Parenthood affiliate that performs abortions and transferred it to research customers, and Planned Parenthood Orange and San Bernardino Counties ("PPOSBC"), violated various provisions of state law, including but not limited to the California Sales and Use Tax Law.

History & Business Models of DaVinci & DVB

DaVinci Biosciences, LLC, was founded as a for-profit corporation. DaVinci filed its incorporation papers with the California Secretary of State on December 19, 2007.[1] It originally was located at [redacted].[2] As of this August 2016, however, it had moved to [redacted].[3] DVB was also founded as a for-profit

[1] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov (last visited Oct. 21, 2016).
[2] *Id.*
[3] Letter from [redacted], Vice President of Operations, DaVinci Biosciences, LLC, to Panel staff, Aug. 10, 2016.

corporation and filed its incorporation papers with the California Secretary of State on March 16, 2009.[4] DVB was originally located at the same Yorba Linda location as DaVinci.[5] The counsel for both entities informed the Panel that "DVB is a subsidiary of DaVinci Biosciences, LLC."[6]

Both entities received aborted fetal tissue from the same source. The counsel for both told the Panel, "DVB received fetal tissue exclusively from its parent company, DaVinci. DaVinci itself received fetal tissue exclusively from Planned Parenthood of Orange and San Bernardino Counties. At this time, the Panel has not evidence that DaVinci paid money to Planned Parenthood for the donated tissue."[7]

Documents produced to the Panel from other firms in the fetal tissue industry pursuant to subpoenas demonstrate that the industry norm is for companies, be they for-profit or non-profit, to pay California-based abortion clinics for fetal tissue. For example, StemExpress, LLC, another for-profit tissue procurement firm, paid Planned Parenthood affiliates in California an average of $50 per-specimen obtained.[8] Advanced Bioscience Resources, Inc., a non-profit tissue procurement business, paid facility fees of $55 or $60 per month (depending upon the year) to the Planned Parenthood affiliates and clinics from which it obtained fetal tissue.[9] From 2010 through 2015, StemExpress paid a total of $135,880 to California-based Planned Parenthood affiliates for fetal tissue specimens.[10] Over the same time period, Advanced Biosciences Resources, Inc. paid a total of $328,225 to California-based Planned Parenthood affiliates for fetal tissue specimens.[11]

The contractual agreement between DVB and PPOSBC show that the firm provided PPOSBC "with a sterile container, including storage media, for each" fetal tissue specimen the Planned Parenthood affiliate obtained.[12] On each day DVB was scheduled to obtain fetal tissue, PPOSBC workers would, "following retrieval, store each [fetal tissue] Specimen in a separate container" and "notify DVB's "designated contact. . . that Specimen is ready for pick-up . . . ."[13]

Documents produced by DVB show that PPOSCB workers performed the following tasks:

- Discussed tissue donation with women awaiting abortions

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[4] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov (last visited Oct. 21, 2016).
[5] *Id.*
[6] Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel, Jan. 29, 2016, at 1 [hereinafter Burby letter].
[7] *Id.* at 3.
[8] *See* Services Agreement between StemExpress, LLC, and Planned Parenthood Mar Monte, Apr. 1, 2010, at 1 [STEM_HOUSE.SELECT_0167 – STEM_HOUSE.SELECT_0169]; Services Agreement between StemExpress, LLC, and Planned Parenthood Shasta Pacific, May 15, 2012, at 1 [STEM.HOUSE.SELECT_0170 – STEM.HOUSE.SELECT_0172]; Services Agreement between StemExpress, LLC, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties, Oct, 23, 2013, at 1.
[9] Advanced Bioscience Resources, Inc., "Statement of Facility Fees, Jan. 2010 – Oct. 2015."
[10] Panel analysis of invoices from Planned Parenthood Mar Monte and Planned Parenthood Shasta Pacific to Stem Express, LLC.
[11] Panel analysis of invoices from Planned Parenthood San Jose, Planned Parenthood Riverside, and Planned Parenthood to Advance Bioscience Resources, Inc.[date?]
[12] Specimen Donation Agreement between DaVinci Biosciences, LLC, and Planned Parenthood of Orange and San Bernardino Counties, Sep. 23, 2008, at 1, attachment # **TK** . [hereinafter DVB Agreement] [DVB_00001613].
[13] *Id.* at 2 [DVB-00001614].

- Obtained consent from the patients to donate human fetal tissue
- Procured fetal tissue of between a gestational period of 5-20 weeks
- Stored the signed consent forms
- Collected the fetal tissue samples, washed the samples, and transferred them to a sterile container with the gestational age written on the container, and
- Stored the samples on wet ice[14]

DaVinci and DVB sold the fetal tissue to researchers, educational institutions, and pharmaceutical companies. DaVinci "focused on the research and development of cell-based therapeutics targeting neurodegenerative and autoimmune diseases, while DVB supplied human biological tools to academic institutions and pharmaceutical companies for research purposes."[15]

DVB has an online catalog through which researchers can select from among 338 different types of cells and add the desired product to their "cart."[16] The prices range dramatically: bone marrow mononuclear cells sell online for $50;[17] cardiomyocytes for $850;[18] skeletal muscle progenitor cells for $900;[19] glioblastoma multiforme cell (uncultured) FFPE block for $1,200;[20] and synovial tissue FFPE block for $1,750.[21]

The DVB Website catalogue states that customers can "Order anytime, 24 hours a day, 365 days a year by email or fax. If your order arrives outside our normal business hours, it will be quickly processed at the beginning of the next business day."[22] All orders to North America "are shipped from DV Biologics headquarters in Southern California and freight is pre-paid and added to your invoice as a separate item unless customers references their own separate shipping account and vendor."[23] International orders are shipped from DV Biologics headquarters in Southern California every Monday unless specially requested to be shipped on another date.[24]

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[14] DaVinci Biosciences, LLC, "Characterization of Human Fetal Stem Cells and Determination of Research and Therapeutic Tool Potential," undated.
[15] *Id.*
[16] *See:* DV Biologics, LLC, "LIFEbank Products," http://www.dvbiologics.com/products (last visited Oct. 21, 2016).
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] DV Biologics, LLC, Website, http://www.dvbiologics.com/ordering-information (last visited Oct. 25, 2016).
[23] *Id.*
[24] *Id.*

Potential Criminal Violations on the Part of DaVinci & DVB

California Revenue and Tax Code

A provision of the California Revenue and Tax Code states:

> [E]very retailer engaged in business in this state and making sales of tangible personal property for storage, use, or other consumption in this state, not exempted . . . shall, at the time of making the sales or, if the storage, use, or other consumption of the tangible personal property is not then taxable hereunder, at the time the storage, use, or other consumption becomes taxable, collect the tax from the purchaser and give to the purchaser a receipt therefor in the manner and form prescribed by the [California State Equalization Board].[25]

A publication put out by the State Board of Equalization ("SBE") states that provision applies to corporations, individuals, Limited Liability Companies, Limited Liability Partnerships, Limited Partnerships, partnerships, married co-owners, registered domestic partnerships, and organizations.[26]

The law defines a "retailer engaged in business in" California as "Any retailer maintaining, occupying, or using, permanently or temporarily, directly or indirectly, or through a subsidiary, or agent, by whatever name called, an office, place of distribution, sales or sample room or place, warehouse or storage place, or other place of business."[27]

There is an exemption for the sale of human blood and human body parts.[28] DVB is not a tissue or blood bank rather it sells fetal tissue cells, cell lines, and other products directly to customers. SBE recently collected nearly $82,000 for unpaid sales taxes for a non-profit organization that saves dogs, draws blood from those dogs, and sells the white blood cells, plasma, and red blood cells for transfusions into other canines.[29]

The statute defines tangible personal property as "personal property which may be seen, weighed, measured, felt, or touched, or which is in any other manner perceptible to the senses."[30] Thus, cells and cell lines are tangible personal property under the California Sales and Use Tax.

The SBE publication further states that California companies can pass along the amount of sales tax to customers, provided the business lists a separate amount for sales tax reimbursement on its receipts or invoices, or if the sales agreement "specifically calls for the addition of sales tax

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[25] Cal. Rev. & Tax Code § 6203.
[26] Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 1. [hereinafter Pub.. 72].
[27] Cal. State Bd. of Equalization, "Laws, Regulations & Annotations, Sales and Use Tax Law, Chapter 3. The Tax," https://www.boe.ca.gov/lawguides/business/current/btlg/vol1/sutl/6203.html (last visited Oct. 25, 2016).
[28] Cal. Rev. & Tax Code § 33 ("Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.").
[29] Chris Haire, "Greyhound Dog Rescue Hemopet Fights to Stay Open after $82,000 Tax Bill," *Orange County Register*, Oct. 10, 2016, http://www.ocregister.com/articles/blood-731674-hemopet-greyhounds.html (last visited Oct. 27, 2016).
[30] Cal. Rev. & Tax Code § 6016.

reimbursement."[31] If the business includes sales tax reimbursement in its prices, companies "must inform the buyer that tax is included" by making one of the following statements on a price tag or in an advertisement: "All prices of taxable items include sales tax reimbursement computed to the nearest mill," or "The price of this item includes sales tax reimbursement to the nearest mill."[32] Neither of those statements are on DVB's website.

Under the California Revenue and Tax Code,

> Internet sales are treated just like sales made at retail stores, by sales representatives, over the telephone, or by mail order. If your business is located in California, retail sales of tangible personal property that you make over the Internet to California customers are generally taxable unless the sales qualify for a specific tax exemption or exclusion . . . and you are required to register for a permit and report and pay tax to the same extent as any other retailer in California.[33]

As previously noted, DVB sold its products through the Internet. It should, therefore, have collected tax on sales made to California customers. Ten invoices produced by DVB show the firm did not charge tax to Applied StemCell, Inc., a California-based company ("Applied StemCell"). Applied StemCell filed its incorporation papers with the California Secretary of State on February 13, 2008.[34] Applied StemCell "is a leading stem cell and gene editing company . . ."[35] The invoices are listed in the chart below, and copies are attached to this letter.

DATE	INVOICE NUMBER	TOTAL COST	SALES TAX CHARGED
February 12, 2013	437	$ 82.00	$ 0.00
October 1, 2013	618	$ 450.00	$ 0.00
October 7, 2013	622	$1,570.00	$ 0.00
March 6, 2014	754	$4,016.99	$ 0.00
August 13, 2014	869	$ 592.99	$ 0.00
August 18, 2014	871	$ 856.99	$ 0.00
November 24, 2014	954	$ 410.00	$ 0.00
December 22, 2014	999	$ 82.00	$ 0.00
January 12, 2015	1021	$ 114.00	$ 0.00
February 24, 2015	1077	$1,250.00	$ 0.00

[31] Pub. 72 at 5.
[32] *Id.*
[33] Cal. State Bd. of Equalization, "Publication 109 Internet Sales," https://www.boe.ca.gov/formspubs/pub109/ (last visited Oct. 26, 2016).
[34] Online at http://kepler.sos.ca.gov/ (last visited Oct. 27, 2016).
[35] Applied StemCells, Inc. website, http://www.appliedstemcell.com/ (last visited Oct. 27, 2016).

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether DVB violated the statute, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-907, March.Bell@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

The Honorable Vern Pierson
El Dorado County District Attorney

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

December 1, 2016

VIA EMAIL

The Honorable Ken Paxton
Attorney General
State of Texas
300 W. 15th Street
Austin, TX 78701

Dear Attorney General Paxton:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony that indicates that Planned Parenthood Gulf Coast ("PPGC"), an abortion facility that procured fetal tissue and transferred it to researchers,[1] allegedly violated state law, including but not limited to the Tex. Penal Code § 48.02, and Tex. Penal Code Title 8 § 37.08.

[1] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Interim Update to the U.S. House of Representatives, Jul. 14, 2016, https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20160714Interim_Update.pdf.

Background on Planned Parenthood Gulf Coast

PPGC has a research department[2] that conducted studies for pharmaceutical companies,[3] the medical device industry,[4] and academic institutions, mostly in Texas.[5] PPGC procured fetal tissue for the University of Texas Medical Branch, Galveston.[6] PPGC bought its headquarters in 2010 largely because it met the needs of the research department.[7]

PPGC conducts in-house fetal tissue extraction, processing, storage, and shipping.[8] PPGC also ships tissue, but it requires the study sponsors to set up a FedEx account. PPGC prints the air bill, puts the air bill on the container, places the shipment on dry ice, and either has FedEx pick up the shipments or a PPGC staffer will drop it off.[9] PPGC bills customers for any sterile supplies needed for tissue procurement.[10]

Despite those costs incurred by PPGC, there are indications that PPGC made money from its sales of fetal tissue. [redacted], PPGC's director of research, stated "this research department generates more revenue than the entire OB GYN research program at Baylor [College of] Medicine. . . .multiple, multiple times more revenue."[11]

PPGC Interactions with University of Texas Medical Branch

From 2010 through 2011, PPGC procured fetal tissue for the University of Texas Medical Branch, Galveston ("UTMB").[12] While PPGC personnel generally obtained consent from patients to donate fetal tissue, and procured the tissue, emails produced by UTMB indicate that its personnel also obtained consent from patients and procured the fetal tissue.

October 20, 2010 email from [redacted]

In an October 10, 2010 email to [redacted] at UTMB, [redacted] wrote:

> We need to renegotiate the budget for both studies based on feedback from [PPGC staff] . . . . here is their proposal:
>
> $50 enrollment/consent process (consent per PPGC SOP, physician statements)[.]

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[2] *See* Center for Medical Progress, "Transcript, Meeting with [redacted], Director of Research, Planned Parenthood Gulf Coast; [redacted], Ambulatory Surgery Director, Planned Parenthood Gulf Coast; [redacted], Physician, Planned Parenthood Gulf Coast; Medical Assistant, Planned Parenthood Gulf Coats; [and] Two Actors posing as fetal tissue procurement company," Apr. 9, 2015, attachment 1. [hereinafter CMP].
[3] *Id.* at 5.
[4] *Id.* at 6.
[5] *Id.* at 35.
[6] Documents produced by University of Texas Medical Branch.
[7] CMP at 96.
[8] *Id.* at 9, 14, 19-20, 29; 31, 40.
[9] *Id.* at 19-20.
[10] *Id.* at 90.
[11] *Id.*
[12] *Id.* at 7.

> $100 room set up/collection (strip machines, sterile equipment, rinse hosing with sterile water, biological sample collection) [.]
>
> $50 enrollment/consenting fee if tech leaves without tissue (staff performed the work and tech didn't/couldn't stay to collect sample).
>
> $2000 annual admin fee (new or retraining staff . . . and Research Mgmt oversight, consent storage, supply storage).
>
> It would also be preferable if we amended the contracts to provision $Xamount/yr for a spend-down grant. PPGC is paid in advance for a set number of samples/yr, and then you collect at will . . .. [13]

UTMB invoices and proposed amended contract

UTMB produced invoices to the Panel from PPGC that show PPGC billed UTMB a total of $21,424.98 in annual administrative fees, consent payments, staff training, and supplies.[14]

An unexecuted amended contract between PPGC and UTMB would have provided for the college to pay PPGC $150 for each executed informed consents of patients (up to 500 patients), plus $2,000 in annual administrative fees, and $1,500 for training UTMB staff.[15] Had the contract been executed as drafted, PPGC would have received $75,000 solely for consent forms signed by patients.

April 2011 Planned Parenthood Federation of America memo on fetal tissue donations

On April 4, 2011, Planned Parenthood Federation of America ("PPFA")'s senior director for public policy litigation and law sent a memorandum to affiliate chief executives, affiliate medical directors, and patient service directors, on federal regulations for participation in fetal tissue donation programs.[16] The memorandum notes that applicable federal laws "forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit 'reasonable payments associated with the transportation, implantation, processing, perseveration, quality control, or storage' of fetal tissue."[17]

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[13] Email from [redacted] to [redacted], Re: Study, Oct. 1, 2010, attachment 2. [UTMB 321-322].
[14] Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Nov. 11, 2010 [UTMB 328]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Nov. 11, 2010 [UTMB 329]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Jun. 11, 2011 [UTMB 344]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch, Sep. 29, 2011 [UTMB 252], attachment 3.
[15] Tissue Supply and Biological Specimen Agreement, Amended No. 2, between Planned Parenthood Gulf Coast, Inc. and [redacted] of University of Texas Medical Branch, Jul. 26, 2011, attachment 4. [UTMB 299-301].
[16] Memorandum from [redacted], Public Policy Litigation and Law, Planned Parenthood Federation of America; [redacted] Acting Vice President for Medical Affairs, Planned Parenthood Federation of America; and [redacted], Vice President for Medical Services, Planned Parenthood Federation of America; to Affiliate Chief Executives, Affiliate Medical Directors, [and] Patient Service Directors, Re: Federal regulations for aborted pregnancy tissue donation programs, Apr. 4, 2001, attachment 5. [PPFA-HOU_E&C-000148 – 000150] [hereinafter [redacted] memo].
[17] [redacted] memo [PPFA-HOU_E&C-000149].

The memorandum states that PPFA affiliates "can chose one of two methods to comply with these laws."[18] The methods outlined in the memorandum are:

> One method would be to recover no costs associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.
>
> . . . The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred by the affiliate in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.
>
> Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a credible and good-faith computation of the actual cost of the space occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.[19]

The memorandum goes on to "remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well."[20]

January 2011 redistribution of PPFA memo on fetal tissue donation

The April 2001 memorandum was redistributed to PPFA affiliates in January 2011 under the signature of [redacted], then then senior PPFA director for clinical services.[21] The memorandum from [redacted] sought

> . . . to remind affiliates about the federal law relating to payment for participation in such programs. The attached memo was sent almost exactly 10 years ago (yikes!).

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[18] [redacted] memo [PPFA-HOU_E&C-000150].
[19] *Id.*
[20] *Id.*
[21] Memorandum from [redacted] Senior Director, Clinical Services, Planned Parenthood Federation of America; [and] [redacted] Director, Clinical Services, Planned Parenthood Federation of America; to Affiliate Medical Directors, [and] Patient Services Directors, Re: Aborted pregnancy tissue donation programs, Jan. 26. 2011, attachment 6 [PPFA-HOU_E&C-000146].

> Given the time that has elapsed and that there has likely been staff turnover, we thought it would be helpful to resend it to assure continuing compliance with the statutes."[22]

PPFA affiliates, including PPGC, were, thus, twice put on notice about the steps they would have to undertake in order to participate in a fetal tissue donation program, and ensure that any reimbursable costs they received did not constitute valuable consideration under the applicable federal and state laws.

Despite that knowledge, the Panel has learned that the costs included in PPGC's contract and proposed contract with UTMB were based not on an independent auditor's credible and good-faith analysis of the actual costs it incurred to procure fetal tissue for UTMB. Rather it was based on back-of-the-envelope calculations by a single PPGC official. The fact that PPGC ignored the long-standing advice of PPFA's legal director when it drafted the UTMB contract and proposed amendment goes directly to PPGC's knowledge of the duty to comply with the applicable law and its willful decision to ignore the legal advice of its organization.

PPGC Interactions with Baylor College of Medicine

Documents produced by the Baylor College of Medicine ("BCM") show that for more than two years, from November 1, 2014 through November 4, 2015, PPGC entered into negotiations to procure fetal tissue for BCM.[23] Those documents show that PPGC assisted BCM with proposals that would be acceptable to the Institutional Review Board ("IRB") at BCM.

November 1, 2014 email from [redacted] of PPGC to [redacted] BCM, a copy of which was sent to [redacted], PPGC's medical director, and [redacted]

The email states [redacted] was "putting" [redacted] "in touch with our Medical Director [redacted], who oversees all research, as well as our Research Director [redacted] who will be your primary contact person during the IRB approval/coordination phase."[24]

March 24, 2014 email from [redacted] to [redacted]

[redacted] wrote: "Thank you for speaking with me today, and for your help with the IRB. Attached, please find my original [IRB] submission, the [PPFA] consent form draft, and the response from the IRB. . . .Please feel free to contact me any time with any questions you may have."[25] Later that same day, [redacted] replied, "Yes, we can do that."[26] [redacted] asked, "Would you have time to speak to me on Friday to discuss the IRB comments?"[27] [redacted] stated, "I can be available Monday."[28]

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[22] *Id.*
[23] Documents produced by Baylor College of Medicine.
[24] Email from [redacted] to [redacted], cc: [redacted] [redacted] RE: IRB Pediatrics BCM, Nov. 1, 2013, attachment 7.
[25] Email from [redacted] to [redacted], Subject RE: IRB pediatrics BCM, Mar. 2014, attachment 8.
[26] Email from [redacted] to [redacted], May 20, 2014, 4:51 PM, attachment 8.
[27] Email from [redacted] to [redacted], Subject: Re: IRB pediatrics BCM, Jun. 3, 2014, 6:38 PM, attachment 8.
[28] Email from [redacted] to [redacted] Jun. 6, 2014, 3:07 PM, attachment 8.

May 20, 2014 email from [redacted] to [redacted]

[redacted] sent an email to [redacted] on May 20, 2014 that stated, "I have received the following response to my IRB submission from BCM, and am wondering if you could comment on the bolded sections."[29]

October 20, 2014 email from [redacted] to [redacted]

In an October 20, 2014 email exchange, [redacted] an assistant to [redacted] emailed [redacted] in which she stated, "I want to follow up once more to see if it would be possible to set [up] a time to touch base over the phone sometime this week. I have spoken to our local IRB and need your approval/guidance before I proceed."[30]

October 20, 2014 email from [redacted] to [redacted]

[redacted] replied: "Yes, that would be fine. I have some this afternoon at 2pm. Would that work for you?"[31]

October 20, 2014 email from [redacted] to [redacted] regarding assigned tasks to assist IRB

On October 20, 2014, [redacted] again emailed [redacted]:

> Dear [redacted]
>
> Thank you so much for the productive phone call. I spoke with [redacted] after our phone call ended and she was really excited to know we had made so much progress. I have outlined some of her comments/feedback below in red:
>
> Key Discussion Items (Assigned party):
>
> • Check with PPFA if we can use the generic tissue procurement consent or do we need a site-specific IRB approved consent form [redacted] [sic] – Generic Information/Release/Acknowledgement form is acceptable. Please move forward with submission of the attached form to the IRS for approval. [sic]
>
> • Develop a budget/contract describing the scope of work and approximate time/effort it will take to execute the study. [redacted] will send us a sample contract she executed with UT Galveston. [redacted] [sic] – I can't provide this yet as the details of the project that need to be referenced in the contract are still being negotiated. We will need to make specific reference to the fact no remuneration for specimens will occur. Administrative costs only will be included in a budget. [sic]

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[29] Email from [redacted] to [redacted], Subject: Re: IRB pediatrics BCM, May 20, 2014, 11:12 AM, attachment 9.

[30] Email from [redacted] to [redacted], cc: [redacted], Subject: Pediatrics research proposal – [redacted] Baylor College of Medicine, Oct. 20, 2014, 8:34 AM, attachment 10.

[31] Email from [redacted] to [redacted], cc: [redacted], Subject: RE: Pediatrics research proposal – [redacted] Baylor College of Medicine, Oct. 20, 2014, 8:42 AM, attachment 10.

• [redacted] needs to provide a description of how the tissue should be collected, processed, stored, and transported.

1. RESPONSE [sic]: [redacted] would like the fetal cadaveric tissue transported on ice to our site. However, she would like to know if Planned Parenthood would be willing to separate out and send the brain, thymus, spleen and liver and how much would this process cost us? PPGC is unable to dissect the tissue per request. It is also important to understand PPGC performs D&E's so that there's disarticulation versus a whole fetus. [sic]

• Discuss the new gestational age calculation per TX state regulations with [redacted]. [redacted] will provide us with the new gestation age calculation formula. [redacted] The new state limit is 20 weeks post fertilization so 21.6wks LMP, which is how we calculate and our ultrasound machines are calibrated. Therefore, we could collect samples between 20-21.6wks [sic]
• [redacted] would like to have [redacted] and her team over for a meeting before the study is ready to get started. RESPONSE: [redacted] agrees with the idea. [sic][32]

Draft contract between PPGC and BCM

BCM produced copies of a draft contract with PPGC for the procurement of fetal tissue that were never executed to the Panel. Under the proposed terms, BCM would have been required to pay PPGC $5,700 for 25 executed informed consents, plus "$50 staff time expense involved in obtaining consent and relevant study documentation. This includes consents for which no sample is obtained. Planned Parenthood [Gulf Coast] will consent up to 500 patients,"[33] reimbursement of $100 per-informed consent for sterile procedure room set-up and sample collection, and annual administrative fees of $2,000 for "Surgical Services and Research Management oversight, consent storage, and supply storage. This list is not all inclusive."[34] Had the contract been executed, BCM would have paid PPGC up to $25,000 for 500 consents.

November 17, 2014 email from [redacted] to [redacted]

On November 17, 2014, [redacted] sent [redacted] an email, the subject of which was to "Pediatrics Research Proposal – [redacted]/Baylor College of Medicine – IRB Approval Obtained," that stated: "First, I would like to thank you for your support through our IRB review process . . .. Our IRB proposal for your outlining the study procedures/objectives is also attached for your reference. Lastly, I submitted the clinical consent you provided for tissue donation (attached) to BCM IRB and it was deemed acceptable for use."[35]

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[32] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted]/Baylor College of Medicine, Oct. 20, 2014, 3:10 PM, attachment 11. (emphasis and red highlights in original).
[33] Tissue Supply and Biological Specimen Agreement between Planned Parenthood Gulf Coast, Inc. and Baylor College of Medicine, attachment 12.
[34] *Id.*
[35] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted]/Baylor College of Medicine – IRB approval obtained, Nov. 17, 2014, 10:31 AM, attachment 13.

November 17, 2014 email from [redacted] to [redacted]

[redacted] replied "Thank you!"[36]

Emails demonstrating PPGC knew that BCM IRB approved the fetal tissue research proposal

Multiple email exchanges between [redacted] and persons at BCM show that PPGC knew the BCM IRB had approved the proposal. For example: On July 7, 2015, [redacted] sent an unknown document to [redacted];[37] [redacted] replied, "Just to clarify, you would like me to insert specifics on the experiments we plan to perform and replace the highlighted text with that corrected version of our experimental plans?"[38] [redacted] stated, "Yes, please insert any language that is pertinent to the project – this was meant to be a reference only."[39]

Center for Medical Progress videotapes

On July 14, 2015, the Center for Medical Progress ("CMP") began its release of videotapes obtained during the course of its 30-month long investigation into the sale of fetal tissue by PPFA affiliates to tissue procurement companies.[40] The release of the videos prompted several congressional investigations, and led to the Panel's creation by the U.S. House of Representatives.[41] The timing behind the start of CMP's release of its videotapes is relevant in light of how PPGC ended its negotiations with BCM.

October 13, 2015 email from [redacted] to [redacted]

On October 13, 2015, [redacted] sent [redacted] an email in which she stated:

> Hello [redacted] I hope that you are well and had a great weekend.
>
> In light of recent events, do we need to make a change to our contract?
>
> I still very much believe in the value of my NIH funded studies, and would very much like to proceed it this is possible.[42]

November 4, 2015 email from [redacted] to [redacted]

[redacted] did not reply until November 4, 2015, when she stated:

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[36] Email from [redacted] to [redacted], Nov. 17, 2014, 12:01 PM, attachment 13.
[37] Email from [redacted] to [redacted], Jul. 7, 2015, 4:32 PM, attachment 14.
[38] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted] Baylor College of Medicine – IRB approval obtained, Jul. 7, 2015, 4:40 PM, attachment 15.
[39] Email from [redacted] Jul. 7, 2015, 4:43 PM, attachment 15.
[40] *See* Center for Medical Progress website, http://www.centerformedicalprogress.org/human-capital/ (last visited Nov. 2, 2016).
[41] *Supra* note 1.
[42] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted] Baylor College of Medicine – IRB approval obtained, Oct. 13, 2015, 2:59 PM, attachment 16.

[redacted],

> To clarify: we do not have a valid contract, and I did not offer you a contract. I previously provided some exemplar language that should have been included in any contract regarding feta l tissue with the expectation that BCM Grants and Contracts or a BCM attorney would draft a complete contract for both parties to review.
>
> PPGC will not commit to engage in any fetal tissue research endeavors at this time.
>
> I encourage all academic researchers to escalate their need for donated fetal tissue to their department chair, IRB chairs, chancellors, etc. Academic institutions in Texas cannot remain publically silent regarding their need for donated feta l tissue in research, yet have expectations that research collaboration with Planned Parenthood will remain intact.[43]

October 22, 2015 visit by Texas law enforcement to PPGC

On October 22, 2015, nearly a year after PPGC learned that BCM's IRB had given its approval[44] and [redacted] sent her email to [redacted] in which she stated that PPGC would not commit to engage in any fetal tissue research endeavors at this time,[45] representatives of the Texas Department of Public Safety Texas Ranger Division, the House Police Department homicide division, and the Harris County district attorney's office visited PPGC headquarters to investigate allegations that PPGC may have violated Tex. Penal Code 48.02[46] The report refers to PPGC as GCPP.

During the course of this visit, PPGC's attorney introduced the law enforcement representatives to [redacted], who the attorney described as being a "Long time Baylor employee" who "had been instrumental in building the current research program."[47] The Texas Department of Public Safety Texas Ranger Division report stated that:

> [PPGC's attorney] advised that the last collected fetal tissue specimen collected by GCPP for a scientific study was on 07-26-2011, for the University of Texas Medical Branch. GCPP was recently approached by the Baylor College of Medicine and Rice University for fetal tissue studies. **The Institutional Review Board had not yet given approval for the Baylor or Rice studies.**[48]

The emails cited above demonstrate that [redacted] and potentially other PPGC officials knew that BCM's IRB had approved the research project, despite representations of PPGC's attorney to Texas law enforcement officials that no IRB approval had been obtained by BCM. In addition,

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[43] Email from [redacted] to [redacted], Subject: RE: Pediatrics research proposal – [redacted] Baylor College of Medicine – IRB approval obtained, Nov. 4, 2015, 2:59 PM, attachment 17.
[44] Attachments 14, 15, 16, 17.
[45] Attachment 17.
[46] *See* Tex. Dept. of Pub. Safety Tex. Ranger Div., Report of Investigation, attachment 18.
[47] *Id.*at 2, paragraph 3.5.
[48] *Id.*at 4, paragraph 3.17. (emphasis added).

the Panel has learned that the release of the CMP videotapes was the reason that [redacted] cancelled the negotiations with BCM, and sent her November 4, 2015 email.

Potential Violations of Texas Law

Prohibition of the Purchase and Sale of Human Organs

The Texas Penal Code makes it a misdemeanor if anyone "**knowingly or intentionally offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers** any human organ for valuable consideration."[49] Under the statute, "valuable consideration" does not include "a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services," "reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the organ;" or "reimbursement of expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ."[50]

The statute defines a human organ as "the human kidney, liver, heart, lung, pancreas, eye, bone, skin, **fetal tissue**, or any other human organ or tissue, but does not include hair or blood, blood components (including plasma), blood derivatives, or blood reagents."[51]

False Report to Peace Officer, Federal Special Investigator, or Law Enforcement Employee

The Texas Penal Code likewise makes it a misdemeanor for a person to lie to a law enforcement officer. The law states:

> A person commits an offense if, with intent to deceive, he knowingly makes a false statement that is material to a criminal investigation and makes the statement to: . . . a peace officer or federal special investigator conducting the investigation; or . . . any employee of a law enforcement agency that is authorized by the agency to conduct the investigation and that the actor knows is conducting the investigation.[52]

[49] Tex. Penal Code § 48.02(b). (emphasis added).
[50] Tex. Penal Code § 48.02(c).
[51] Tex. Penal Code § 48.02(a). (emphasis added).
[52] Tex. Penal Code Title 8, § 37.08.

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether PPGC violated these statutes, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chairman
Select Investigative Panel

Attachment

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

November 30, 2016

VIA EMAIL

Mr. Michael Hestrin
District Attorney
County of Riverside
3960 Orange Street
Riverside, CA 92501

Dear District Attorney Hestrin:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that Advanced Bioscience Resources (ABR) allegedly violated state law, including but not limited to the Cal. Health & Safety Code § 125320(a) and the California Penal Code § 367f(a), which forbid the transfer of fetal tissue for valuable consideration.

Among the abortion clinics from which ABR procured fetal tissue was Planned Parenthood of the Pacific Southwest,[1] located at [redacted], which has clinics throughout the region, including Planned Parenthood – Riverside Family Planning Center, located at [redacted].[2]

[1] Planned Parenthood Federation of America, Production to the Subcommittee on Oversight and Investigations of the US House of Representatives Energy and Commerce Committee, Aug. 20, 2015 (PPFA-HOU_E&C-000162).
[2] Planned Parenthood of the Pacific Southwest Website, https://www.plannedparenthood.org/planned-parenthood-pacific-southwest, last accessed Oct. 25, 2016.

Background on ABR

ABR, a non-profit organization, obtains fetal tissue from abortion clinics and offers it for resale to researchers. It pays the clinics "a flat fee for services on a product of conception (POC) basis, regardless of how many, or what type, of specimens are procured . . . ."[3] The fees range from $45 to $60, depending upon the year and the clinic.[4] The tissue is obtained by ABR tissue technicians who work in the abortion clinics; the technicians harvest, package, and ship the tissue to the researchers.[5] The abortion clinic staff obtains consent from the patients for fetal tissue donations.[6]

ABR's Interactions with Planned Parenthood Affiliates

ABR had contractual relationships with Planned Parenthood of San Diego and Riverside Counties (now called Planned Parenthood of the Pacific Southwest):

> Planned Parenthood of San Diego and Riverside Counties entered into an agreement with a TPO in June 1999 to facilitate fetal tissue donation by its patients. That affiliate changed its name to Planned Parenthood of the Pacific Southwest, and renewed the tissue donation agreement, in October 2010. The affiliate's participation in the program is ongoing. Planned Parenthood of San Diego and Riverside Counties also received approval for a research program involving fetal tissue donation in October 2008. That program is ongoing through Planned Parenthood of the Pacific Southwest as well.[7]

ABR Payments to the Abortion Clinics, Including Planned Parenthood Affiliates

During 2015, ABR made nearly $80,000 in payments to its top five abortion clinic sources from which it procured human fetal tissue. ABR claims that it paid the clinic for the "costs for clinical staff obtaining consents, maintaining records, transferring fetal tissue, clinical space, and utilities."[8]

ABR paid Planned Parenthood of Riverside $23,460 in 2015.[9] Furthermore, starting in January 2012, ABR paid Planned Parenthood Pacific Southwest for rented space two days a week for $1,000; if ABR only used the space for one day, it paid $500.[10]

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[3] Advanced Bioscience Resources, Inc., "ABR Overview: Key Points," at 5 (SP000752).
[4] Advanced Bioscience Resources, Inc., Production to the Subcommittee on Oversight and Investigations of the US House of Representatives Energy and Commerce Committee, Sept. 3, 2015 (HCEC000028 – 41).
[5] Advanced Bioscience Resources, at 7 (SP000754).
[6] Advanced Bioscience Resources, at 5 (SP000752).
[7] Planned Parenthood Federation of American (PPFA-HOU_E&C-000162). *See* Advanced Bioscience Resources, Inc., (HCEC000028 – 41).
[8] ABR Overview: Key Points, at 5 (SP000752).
[9] Advanced Bioscience Resources, Production to the Select Investigative Panel of the US House of Representatives Energy and Commerce Committee, June 7, 2016 (SP000817-826).
[10] Advanced Bioscience Resources (HCEC000039).

Potential Violations of Law

Under 42 U.S.C. § 289g-2, it is unlawful for any person to "knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce." The term valuable consideration "does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue." Anyone who violates this law is subject to a fine "not less than twice the amount of the valuable consideration received" and/or imprisonment for up to ten years.

California state law includes a nearly identical prohibition. Under Cal. Health & Safety Code § 125320(a), a "person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes." Virtually identical to the abovementioned federal statute, the California statute states that "'valuable consideration' does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part."[11]

Similar provisions in the California Penal Code § 367f(a) prohibit the acquisition, sale, or transfer of "any human organ, for purposes of transplantation, for valuable consideration," subject to a fine of up to $50,000 and imprisonment for up to five years.

To the extent any of payments to the Planned Parenthood affiliates or the other abortion clinics occurred for purposes of transplantation, ABR and any of its business partners so involved would additionally be in violation of California Penal Code § 367f(a).

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether Advanced Bioscience Resources violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

[11] Cal. Health & Safety Code § 125320(b).

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

November 30, 2016

Via Email

The Honorable Pam Bondi
Attorney General
Office of Attorney General
State of Florida
The Capitol PL-01
Tallahassee, FL 32399-1050

Dear Attorney General Bondi:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion businesses and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received information indicating that Presidential Women's Center, Inc. ("PWC"), at least in part through its relationship with StemExpress, LLC ("StemExpress"), a firm that procures fetal tissue from abortion businesses and transfers it to research customers, violated various provisions of federal and state law, including but not limited to 42 U.S.C. § 289g-2 and Fla. Stat. § 873.05, which forbid the transfer of fetal tissue for valuable consideration.

StemExpress's Business Model and Growth Strategy

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Under its business plan, StemExpress recruited and screened businesses that were most likely to perform abortions that could produce saleable tissue to researchers.[1] The company sought information about the number of abortions the businesses performed each week, the gestational age of fetuses scheduled to be aborted, the days the abortions were done, whether

[1] StemExpress Website Recruitment Form for Abortion Clinics, attachment 1.

digoxin[2] was used (which would taint the tissue and, thus, render the baby useless for obtaining tissue), and, if so, at what age it was used. Researchers ordered tissue using StemExpress's website. The firm initially had a drop-down menu that allowed researchers to obtain various types of tissue.[3] It later switched to another web-based system.

In order to harvest the tissue at PWC, a typical work day for PWC staff went as follows:

- At the beginning of the day, PWC staff logged into the StemExpress Daily Task Page website, which included the day's orders for certain baby body parts and the gestation period, letting PWC staff know what they needed to harvest that day.[4]

- Next PWC staff met with the patients waiting to be prepped for their abortions, and convinced them to consent to donate by saying that the donation will help cure diabetes, Parkinson's, and heart disease.[5]

- After an abortion, PWC staff collected the baby's remains and procured the body parts that were ordered.[6] PWC staff then packed the tissues or body parts, and shipped them directly to the customer via FedEx.[7]

- Throughout the day, PWC staff updated the StemExpress Daily Task Page website, informing both StemExpress and all other participating abortion businesses' staff of certain patient details via their responses to certain requests.[8]

- PWC staff further shared details from patients' private medical files with StemExpress via forms such as the StemExpress form "Patient and Sample Information Form for Research Study," which asks for the following patient information: name or kit ID, mother's date of birth, mother's ethnicity, date collected (i.e., date of abortion), and gestational age at time of blood draw.[9] The form admonishes, "Please fill out and return with the samples to ensure timely compensation!"[10] Other information appearing on StemExpress Researcher Procurement Forms includes patient height, patient weight, patient smoking history,[11] and

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[2] Digoxin is a heart medication that sometimes is injected into the amniotic fluid or fetus to cause fetal demise before surgical or induction abortion. *See* Abortion in California: A Medical-Legal Resource, *available at* http://californiaabortionlaw.com/wp/?page_id=135.
[3] StemExpress Drop-Down Ordering Menu, attachment 2.
[4] PWC00046, PWC00023-PWC00024.
[5] BioMed IRB Informed Consent to Participate in a Clinical Research Study, Sponsor: StemExpress, LLC, attachment 3; *see also* PWC00023.
[6] PWC00023-PWC00024, PWC00040-PWC00042, PWC00054-PWC00057.
[7] PWC00029-PWC00030, PWC00032-PWC00034, PWC00040-PWC00042, PWC00050-PWC00052. FedEx is the primary shipping method for StemExpress samples. FedEx pickups were scheduled every Tuesday and Thursday for Lab #1 specimens, and tissue samples were dropped off directly with FedEx. For each package, the weight was always listed as 4 lbs. *See* PWC00029-PWC00031, PWC00032. One document stated that the declared value should always be $1,250 per sample, PWC00030, and another form indicated that the declared value of blood specimens should be $500 and of tissue specimens, $750. PWC00033.
[8] PWC00046-PWC00048.
[9] PWC00026.
[10] PWC00026.
[11] PWC00027.

> fetal sex.[12] PWC staff further disclosed information from patient data sheets with StemExpress.[13]

StemExpress's stunning revenue growth five years after its formation belies the notion that the firm was not operating for profit. In 2010, its revenue was $156,312; during 2011, that figure more than doubled to $380,000; a year later, in 2012, StemExpress's revenue nearly tripled to $910,000; by 2013, its revenue was $2.20 million; then in 2014, the revenue had once again more than doubled to $4.50 million. Based on its three-year revenue growth of 1,315.9%, *Inc. Magazine* named StemExpress one of the fastest-growing privately held companies in the U.S.[14]

This revenue growth accompanied an aggressive marketing strategy directed toward abortion businesses. StemExpress distributed its brochure at a conference hosted by the National Abortion Federation (NAF). The brochure promised businesses they would be "[f]inancially profitable" if they allowed StemExpress to procure tissue from the businesses. The brochure also said "By partnering with StemExpress" the businesses will not only help research "but [they] will also be contributing to the fiscal growth of [their] own clinic[s]."[15]

When StemExpress was formed, billing records show the firm was procuring fetal tissue from four businesses. By the end of 2014, the firm had "relationships with more than 30 procurement sites across the country."[16] However, many of those procurement sites had multiple locations, making the actual number nearly 100. In 2015, StemExpress tried to execute a contract with NAF that would have given the firm potential access to nearly 200 additional locations. Its overall strategy was to provide on-demand body parts to researchers. In order to do that, the firm needed a ready supply of fetal tissue. The only way to achieve that was to dramatically increase the number of abortion businesses from which it would obtain fetal tissue.

Presidential Women's Center, Inc.'s Contract with StemExpress

On February 14, 2014, PWC signed a contract with StemExpress providing:

> Presidential Women's Center will provide, and StemExpress will pay the reasonable costs for, services and facilities . . . associated with . . . the removal of fetal organs from POCs [(products of conception)]; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal blood; seeking consent for donation of fetal organs and maternal blood from appropriate donors[;] and . . . maintaining records of such consents so that verification of consent can be supported.[17]

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[12] PWC00029.
[13] *See* PWC00029.
[14] *The 500: Get to know the 500 fastest-growing privately held companies in America*, INC., Sept. 2014, at 137.
[15] StemExpress Brochure Distributed at NAF Conference, attachment 6 (key text highlighted).
[16] Complaint at para. 17, StemExpress, LLC v. Center for Medical Progress, No. BC-589145 (L.A. Super. Ct. filed Jul. 27, 2015).
[17] PWC0001.

In return, StemExpress contracted to pay PWC $50.00 per 60ccs of maternal blood and $75.00 for the collection of fetal tissue, if the collection was handled solely by PWC staff. If StemExpress staff participated in the collection, these payments were reduced. PWC agreed to invoice StemExpress monthly by number of tissue and number of maternal bloods procured.[18]

PWC agreed to allow StemExpress access to patients' charts and identity of donors "as necessary to obtain patients' consent for use of POCs and maternal bloods."[19]

Presidential Women's Center, Inc.'s Profit

PWC billed StemExpress for the following amounts, and indicated that it was paid for the total amount, other than $300.00 related to the 1/5/2016 invoice. Based on both the invoices and the "Protocol for Stem Express Research,"[20] it appears that PWC provided only fetal livers and villi to StemExpress.[21]

[18] PWC0001.
[19] PWC0002: "StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods."
[20] PWC00024.
[21] It may also have provided placenta at some point. *See* PWC00029.

INVOICE DATE	ITEM	COST PER ITEM	TOTAL INVOICE AMOUNT
4/25/2014	POC x3 (2 livers and 1 villi) Maternal blood x18	POC @ $75.00 each Maternal blood @ $50.00 each	$1,125.00
5/9/2014	POC x3 (3 livers) Maternal blood x16	POC @ $75.00 each Maternal blood @ $50.00 each	$1,025.00
5/23/2014	POC x3 (3 livers) Maternal blood x8	POC @ $75.00 each Maternal blood @ $50.00 each	$625.00
6/12/2014	POC x1 (1 liver) Maternal blood x6	POC @ $75.00 each Maternal blood @ $50.00 each	$375.00
6/20/2014	Maternal blood x6	Maternal blood @ $50.00 each	$300.00
7/19/2014	Maternal blood x14	Maternal blood @ $50.00 each	$700.00
8/1/2016	POC x2 (2 livers) Maternal blood x10	POC @ $75.00 each Maternal blood @ $50.00 each	$650.00
8/28/2014	Maternal blood x13	Maternal blood @ $50.00 each	$650.00
9/9/2014	POC x1 (1 liver) Maternal blood x11	POC @ $75.00 each Maternal blood @ $50.00 each	$625.00
10/31/2014	POC x6 (6 livers) Maternal blood x12	POC @ $75.00 each Maternal blood @ $50.00 each	$1,050.00
11/26/2014	POC x1 (1 liver) Maternal blood x14	POC @ $75.00 each Maternal blood @ $50.00 each	$775.00
1/13/2015	Maternal blood x10	Maternal blood @ $50.00 each	$500.00
1/31/2015	Maternal blood x15	Maternal blood @ $50.00 each	$750.00
3/5/2015	unknown[22]		$1,450.00
4/30/2015	POC x12 (4 livers and 8 villi) Maternal blood x18	POC @ $75.00 each Maternal blood @ $50.00 each	$1,800.00
7/3/2015	POC x16 (4 livers and 12 villi) Maternal blood x28	POC @ $75.00 each Maternal blood @ $50.00 each	$2,600.00
8/3/2015	POC 11 (1 liver and 10 villi) Maternal blood x14	POC @ $75.00 each Maternal blood @ $50.00 each	$1,525.00
9/2/2015	POC x12 (3 livers and 9 villi, including that from twins) Maternal blood x11	POC @ $75.00 each Maternal blood @ $50.00 each	$1,450.00
1/5/2016	unknown[23]		$2,625.00
TOTAL			**$20,600.00**

[22] PWC did not provide this invoice in response to the Panel's Request No. 2.
[23] PWC did not provide this invoice in response to the Panel's Request No. 2.

Unsurprisingly, PWC indicated that they "prefer patients consent to both" blood and tissue donation, though they indicate that they would accept consent for blood only.[24]

StemExpress's Profit and Loss

StemExpress paid $75.00 for each fetal tissue sample it obtained from abortion businesses, and then transferred them to researchers for $595 to $910 per tissue or body part.

Payments from Customers to StemExpress

Customer	Date	Item	Cost
Redacted by StemExpress	September 25, 2014	Human Fetal Tissue	$5,950.00
Redacted by StemExpress	September 25, 2014	Packaging- Gel Pack or Wet Ice	$150.00
Redacted by StemExpress	September 25, 2014	Local Delivery Flat Rate	$2,250.00
		Estimated Tax	$730.64
TOTAL:			**$9,080.64**
Redacted by StemExpress	November 14, 2014	Human Fetal Brains	$3,340.00
		Estimated Tax	$292.25
TOTAL:			**$3,632.25**
Redacted by StemExpress	December 16, 2014	Human Fetal Tissue (upper and lower limbs with hands and feet)	$890.00
Redacted by StemExpress	December 16, 2014	Human Fetal Tissue (calvarium matched to upper and lower limbs)	$595.00
		Estimated Tax	$129.95
TOTAL:			**$1,614.95**
Yale University	January 19, 2012	Fetal Brain Procurement	$2,860.00
Yale University	January 19, 2012	FedEx Priority Overnight	$85.00
Yale University	January 19, 2012	FedEx Priority Overnight	$85.00
Yale University	January 19, 2012	Fetal Brain Procurement	$2,145.00
Yale University	January 19, 2012	Credit for samples	-$2860.00
Yale University	January 19, 2012	Credit for FedEx	-$85.00

[24] PWC00023.

Customer	Date	Item	Cost
TOTAL:			**$2,230.00**

Attached is a sample of a StemExpress invoice to a customer.[25] A comparison of invoices, attorney-created accounting documents, and productions from multiple StemExpress customers shows that the firm may have made a profit when procuring and transferring fetal tissue, and passed a portion of that profit along to the businesses from which it obtained its tissue and blood specimens. The Panel's cost analysis shows StemExpress overstated some of its labor costs, and claimed as expenses shipping, supplies, and infectious disease screenings. These were costs charged to researchers.

[25] Sample StemExpress Invoice to Customer, attachment 7.

COMPARISON OF STEMEXPRESS COST ANALYSIS WITH GENERALLY ACCEPTED INDUSTRY STANDARDS FOR ONE UNIT OF FETAL TISSUE IN 2013

COST ITEMS AND ESTIMATE PRODUCED BY STEMEXPRESS

ADJUSTED BASED ON REASONABLE INDUSTRY STANDARDS

COSTS ALLOCATED TO MATERNAL BLOOD ESTIMATED AT 50%

Cost Item	Description	Estimated Time	Estimated Cost/Expense	Recalculated Time	Recalculated Cost/ Expenses	½ Costs for Maternal Blood
Procurement Management Labor	Receive and evaluate purchase order, enter into Computer system and task board, assign to clinics.	1 hour x $35	$25.00	.5 hour x $35	$12.50	$ 6.25
Packaging Supplies Labor	Packaging all supplies needed for procurement.	1 hour x $10	$10.00	.5 hour x $10	$5.00	$2.50
Shipping	Supplies to Clinic	N/A	$15.00		$15.00	$7.00
Mileage	Mileage paid to technician (.56/mile)	N/A	$75.00		$75.00	$35.00
Supply cost	Box, conical tube, media, petri dish, labels, biohazard bag, gel packs, etc.	N/A	$30.00		$30.00	$15.00
Technician Base Labor	Patient consent, procurement, paperwork packaging.	8 hour x $10	$80.00	1 hour x $10	$10.00	$5.00
Technician Supplemental Compensation	Technician Supplemental Compensation	N/A	$30.00		$0.00	$0.00
Clinic Reimbursement	Technician space, storage of supplies, blood draw chair usage, consent space	N/A	$55.00		$55.00	$27.50
Infectious Disease Draw	Supplies: tubes, labels, needle, biohazard bag, etc.	N/A	$15.00		$15.00	$7.50
Infectious Disease Screening	Screening for HIV, HepB, HepC, LCMV	N/A	$70.00		$70.00	$35.00
Shipping	Average Shipment cost to the Lab (blood and/or tissue)	N/A	$20.00		$20.00	$10.00
Procurement Management Labor	Review paperwork, communications with courier, communications with researcher	1 hour x $35	$35.00		$35.00	$5.00
Product Receipt	Receipt of product at front desk, check into Sage, check into log	1 hour x $15	$15.00	.25 hour x $15	$4.00	$2.00
Inventory & Supply Management	Prorated stores management	1 hour x $20	$20.00	.25 hour x $20	$5.00	$2.50
			$495.00		$351.50	175.75

Attorneys for StemExpress created several cost estimates (orange numbers) that purport to show that Stem Express loses money each time it procures a fetal tissue sample and ships it to a customer. Shown in orange, the cost estimates produced by the attorneys are inconsistent with accounting records produced by StemExpress itself. For example, StemExpress lists **Clinic Reimbursement** which the Panel found was **not** an actual payment made by StemExpress. Also, the costs associated with shipping and infectious disease are passed on to the customer and thus are **not** a cost to StemExpress. Finally, management labor costs at one hour per item ordered, which are counted twice, are dramatically inconsistent with the number of orders actually handled by StemExpress. Similarly, StemExpress estimates do **not** allocate any costs (such as mileage) to maternal blood which is harvested at the abortion business at the same time the human fetal tissue is harvested.

Sample review of a sale of fetal tissue to customer Baylor per invoice #1940 of 1/12/2013
Sale price for Tissue $250.00
Disease screening charged to client $125.00
Shipping charged to client $85.00
Total Revenue obtained from this sale $460.00
Estimated cost of Tissue (per above) $175.75
Excess of revenue over cost $217.00

Sample review of a sale of fetal tissue to customer Baylor per invoice #1940 of 1/12/2013
Sale price for Tissue $250.00
Disease screening charged to client $125.00
Shipping charged to client $85.00
Total Revenue obtained from this sale $460.00
Estimated cost of Tissue (per above) $351.00
Excess of revenue over cost $108.50

Violation of Applicable Laws

Under 42 U.S.C. § 289g-2, it is unlawful for any person to "knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce."[26] The term "'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[27] Anyone who violates this law is subject to a fine "not less than twice the amount of the valuable consideration received" and/or imprisonment for up to ten years.[28]

Florida state law includes a nearly identical prohibition. Under Fla. Stat. § 873.05, a "person may not knowingly advertise or offer to purchase or sell, or purchase, sell, or otherwise transfer, a human embryo for valuable consideration," and further, "may not advertise or offer to purchase, sell, donate, or transfer, or purchase, sell, donate, or transfer, fetal remains obtained from an abortion."

The Florida statute's definition of "valuable consideration" is virtually identical to that of the federal statute.[29] Fla. Stat. § 873.05(3) provides that this activity is a felony of the second degree, and is subject to a fine of up to $10,000 and/or imprisonment for up to 15 years for a first offense.[30]

[26] 42 U.S.C. § 289g-2(a).
[27] 42 U.S.C. § 289g-2(e)(3).
[28] 42 U.S.C. § 289g-2(d).
[29] Such consideration "does not include the reasonable costs associated with the removal, storage, and transportation of a human embryo." Fla. Stat. § 873.05(1). It may include such costs as associated with a fetus, as well as the other activities for which StemExpress set a flat fee for payment to PWC.
[30] Fla. Stat. § 775.082-083; *see also* Fla. Stat. § 775.084 for sentencing of repeat offenders.

Similarly, Fla. Stat. § 873.01 provides that "no person shall knowingly offer to purchase or sell, or puchase sell, or otherwise transfer, any human organ or tissue for valuable consideration," and further, "no for-profit corporation or any employee thereof shall transfer or arrange for the transfer of any human body part for valuable consideration." The statute lists examples of human body parts that may not be purchased, sold, or transferred in that way, and livers are specifically named. Again, this activity is a felony of the second degree, and is subject to a fine of up to $10,000 and/or imprisonment for up to 15 years for a first offense.[31]

And Fla. Stat. § 390.0111(6) prohibits using "any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation either prior to *or subsequent to any termination of pregnancy procedure* . . . ." (emphasis supplied).

The foregoing analysis establishes with a high level of probability that PWC, at least through its contract with StemExpress, routinely violated 42 U.S.C. § 289g-2 and Fla. Stat. § 873.05. This is established by the transactions involving the transfer of fetal tissue to numerous entities for consideration, via its contract with StemExpress, that exceeded statutorily allowable costs.

Finally, it appears that PWC may be in violation of HIPAA protected health information law, 42 U.S.C. § 1320d-6(a)(3), by disclosing individually identifiable health information to another person, which is usually punishable by a fine of up to $50,000 and/or imprisonment for up to 1 year, but when the personal health information was shared "for commercial advantage," as when PWC transferred protected health information in order to sell fetal tissue, the penalty is a fine of up to $250,000 and/or imprisonment for up to 10 years. In their contract, PWC and StemExpress agreed that HIPAA guidelines applied to patients' information and that the charts were "privileged" and merited "confidentiality,"[32] but based on the information requested on the StemExpress forms, such as "Patient and Sample Information Form for Research Study," described above, it seems that they did not adhere to the law or even to their own internal guidelines.[33] This form admonishes, "Please fill out and return with the samples to ensure timely compensation!,"[34] pressuring PWC to improperly share patient information in order to receive their checks. Less specific information than that on the form has been deemed protected health information in at least some states.[35]

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether Presidential Women's Center, Inc., violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov, or Mary Harned, at (202) 480-7160, Mary.Harned@mail.house.gov.

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[31] Fla. Stat. § 775.082-083; *see also* Fla. Stat. § 775.084 for sentencing of repeat offenders.
[32] PWC0002: "Any information obtained from [PWC] patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. . . . This will always be done in accordance with HIPAA guidelines."
[33] PWC00026.
[34] PWC00026.
[35] *See, e.g., Planned Parenthood of the Great Northwest v. Bloedow*, 350 P.3d 660 (Wash. Ct. App. 2015).

Sincerely yours,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel of
the Committee on Energy and Commerce

The Honorable Vern Pierson
El Dorado County District Attorney

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 Rayburn House Office Building
Washington, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

December 7, 2016

VIA EMAIL

The Honorable Ken Paxton
Office of the Attorney General
300 W. 15th Street
Austin, TX 78711-2548

Dear Attorney General Paxton:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of second- and third-trimester abortion providers and the practices of entities that procure and transfer fetal tissue. This includes investigation of partial-birth abortion and the standard of care for infants who survive the abortion procedure.

Over the course of our investigation, we have collected statements and video from former employees and a patient of [redacted] who allege numerous violations of law at one or more of his clinics, describing the practitioner as conducting himself with depraved indifference to infant life and committing acts of murder.

Allegations Against [redacted]

[redacted] is an abortion provider who has operated at three locations in Houston, Texas, including the Aaron Women's Clinic ("Aaron"), the Texas Ambulatory Surgery Center, and the Women's Pavilion; and at the Northpark Medical Group in Dallas. Several former employees who worked with him at one or more of the Houston locations have come forward alleging numerous violations of law.

According to several of his employees, including *Employee #1* and *Employee #2*, who were medical assistants, and *Employee #3*, who assisted with administrative tasks, numerous patients of [redacted] delivered infants alive prior to their demise, which the doctor himself brought about. Specifically, *Employee #1*, who assisted the doctor in the operating room at Aaron, estimated that "[d]uring a typical week with a full patient load, . . . [redacted] would perform

abortions at 20 or more weeks gestation, *i.e.*, later in the second trimester or in the third trimester, on approximately 40 patients."[1] Of that number, *Employee #1* asserted:

> approximately three or four infants would show signs of life. This typically happened when infants were extracted from the cervix in a breech position. At times, the infant would slide completely out because of the extent of the dilation caused by the laminaria administered to patients. In all such cases, [redacted] would terminate their lives. The signs of life they exhibited would include movement of the stomach as the infant breathed or movement of the toes or fingers.[2]

[redacted] would terminate the lives of these infants, *Employee #1* further alleges based on those incidents she witnessed, by any of several methods, including the following:

> snipping the infant's spinal cord with scissors; cutting the neck with Sopher forceps or similar instruments; twisting the infant's head; using forceps, other instruments, or his finger to crush the "soft spot" of the infant's head, or crushing it by the same means through its stomach; or inserting his finger down its throat. If the infant's cranium was coming out first, he would usually use his index finger to puncture its head, but if it was coming out feet first, he would instead insert an instrument in the back of the infant's head.[3]

Several of the same allegations were also made by *Employee #2*.[4]

Employee #3 was not in the treatment rooms when abortions took place, but she alleges she learned from her coworkers of numerous infants whose lives were terminated by [redacted] after showing signs of life following partial or full extraction from the uterus.[5] On one occasion, she stated that she learned from a coworker of an infant killed by the doctor after surviving an abortion; as he was preparing to put it into a bag for disposal, she maintained, the infant had "opened up his eyes and grabbed his hand."[6]

Employee #1 stated that "[o]f the three to four infants terminated in a typical week by [redacted] while showing signs of life, on average, approximately one or two would be put to death after they had left the birth canal entirely. The balance were terminated while they were partially out of the birth canal."[7] *Employee #1* added that she never observed [redacted] "make an attempt to keep alive or resuscitate any infant who showed any signs of life or to direct anyone else to do so," an observation consistent with *Employee #3*'s understanding.[8]

[1] Affidavit of *Employee #1*, Dec. 5, 2016, ¶¶ 1-2, attachment 1 [hereinafter *Employee #1* Aff.].
[2] *Id.* ¶ 3.
[3] *Id.* ¶ 4.
[4] *See* Redacted video—see key, attachment 2 [hereinafter Redacted video] ("Sometimes he would go through the stomach as well. . . . He would like force it [the instrument] through the stomach . . . and he twists it.") ("he would put, like, his finger . . . through the throat") (statements of *Employee #2*).
[5] Affidavit of *Employee #3*, Dec. 6, 2016, ¶ 2, attachment 3 [hereinafter *Employee #3* Aff.].
[6] Redacted video.
[7] *Employee #1* Aff. ¶ 5.
[8] *Id.* ¶ 5; *Employee #3* Aff. ¶ 2.

Employee #1 also alleged that '[redacted] performed numerous abortions during the third trimester in cases that did not involve any serious threats to the mother's or the infant's health."[9] *Employee #2* asserted, "As long as the patients had the cash, he was going to do it past the 25 weeks."[10] Four photographs identified by *Employee #1* and *Employee #3* as taken in the sterilization room of the Women's Pavilion in 2012 depict the remains of infants clearly in their third trimester when they were allegedly terminated by [redacted].[11] According to *Employee #1*, the tears in the neck line visible in the photos are "inconsistent with" terminations done "while the infant[s were] entirely inside the uterus."[12] Thus, besides being late-term abortions, they were likely either partial-birth abortions or homicides committed after full delivery.

Employee #1 and two other employees at the clinic, *Employee #3* and *Employee #4*, additionally allege that the doctor regularly falsified sonogram results to misrepresent the gestational age of the fetus. Some sonograms, they maintain, would be falsified to "overstate the gestational age of the fetus in order to overbill customers."[13]

In other cases, according to *Employee #1* and *Employee #3*, "sonograms would be falsified to conceal the advanced gestational age of the fetus beyond the legal limit in Texas."[14] *Employee #1* claimed:

> I have witnessed this happen in cases involving fetuses as old as 28 weeks. [redacted] would typically tell his ultrasound technician in cases involving fetuses beyond a certain gestational age to allow him to perform the ultrasound himself; he would then bring the patient an ultrasound picture showing another fetus at the gestational age he was misrepresenting to the patient.[15]

An affidavit from a patient attached hereto alleges another specific case of manipulation: *Patient #1*, a woman who obtained an abortion in 2002 at "24 to 25 weeks" gestation, "worried that I was too far along. The girl doing my ultrasound told me that 'ultrasounds can be manipulated.' The clinic determined me to be 23 weeks."[16] "On two occasions that I witnessed," *Employee #1* also alleges that '[redacted] failed to inform a patient she was pregnant with twins."[17]

According to *Employee #1* and *Employee #3*, the doctor "would regularly make use of pre-drawn medicine," including Demerol and Nubain, "without properly logging or storing it." They added:

> This included improperly storing medicine in a food refrigerator. On one occasion, [redacted] concealed these practices during an inspection from the

[9] *Employee #1* Aff. ¶ 6.
[10] Redacted video.
[11] *Employee #1* Aff. ¶ 6; *Employee #3* Aff. ¶ 3. According to *Employee #3*, the photos were taken July 26, 2012. *Id.*
[12] *Employee #1* Aff. ¶ 6.
[13] *Id.* ¶ 7; *Employee #3* Aff. ¶ 4; Statement of *Employee #4*, Nov. 23, 2012, attachment 4, at 1.
[14] *Employee #1* Aff. ¶ 7; *Employee #3* Aff. ¶ 4.
[15] *Employee #1* Aff. ¶ 7.
[16] Affidavit of *Patient #1*, June 17, 2013, attachment 5.
[17] *Employee #1* Aff. ¶ 8.

> Harris County Public Health office by having a nurse put pre-drawn medicine in basins, which she hid in the trunk of her car while the inspector was present."[18]

Employee #1 and *Employee #3* also allege the doctor failed to keep a registered nurse on site in the recovery room at Aaron, which "left unqualified workers to draw and administer drugs."[19] *Employee #1* added that [redacted] concealed this deficiency from authorities by "hir[ing] a nurse from a temp agency for a few days at a time when a government inspection was scheduled."[20] *Employee #1* recorded examples of storage, recordkeeping, and personnel violations in an undercover video from 2011 attached hereto.[21]

Additionally, according to *Employee #1*:

> [redacted] would regularly fail to observe proper sterilization procedures. This included the doctor's habitual reuse of a bottle of Betadine, which is used for cleaning prior to the procedure, that was not cleaned or stored, and which he handled with his gloved hand for patient after patient when going inside the cervix. Additionally, after removing instruments such as Hawkins-Ambler's dilators and Bierer and Sopher forceps from sterile packages, he would place unused instruments back in the sterile package to use on other patients. He often would do so wearing gloves that he did not change between seeing one patient and another, or between trips to the restroom. . . . Instruments in [redacted]'s clinic were not regularly soaked in sterilizing solutions as they needed to be for specified periods of time in order to be sterile. The exception to this occurred prior to government inspections. The vast majority of the doctor's assistants in the sterilization room were uninformed on proper methods of sterilization. In order to reduce his costs, [redacted] also habitually disposed of biohazardous waste in standard garbage bags instead of sterile bags required for such waste.[22]

The same failure with respect to sterilization was also alleged by *Employee #2*, *Employee #3*, and *Employee #4*.[23]

Violations of Applicable Laws

Federal law makes clear that infants that are born, regardless of whether naturally or by extraction during an abortion, are entitled to the same protections given to every other person. Under the Born-Alive Infants Protection Act of 2002, "every infant member of the species homo sapiens who is born alive at any stage of development" is considered a person.[24] This is so

[18] *Id.* Aff. ¶ 9; *Employee #3* Aff. ¶ 5. *See also* Redacted video.
[19] *Employee #1* Aff. ¶ 10; *Employee #3* Aff. ¶ 6.
[20] *Employee #1* Aff. ¶ 10. For additional information regarding the deficiencies in [redacted] s nursing staff and other allegations regarding possible violations at his clinics, see Statement of *Employee #1* in support of Complaint against [redacted] D.O., Apr. 26, 2010, attachment 6.
[21] Aaron Women's Clinic video by *Employee #1*, attachment 7.
[22] *Employee #1* Aff. ¶¶ 11-12. See also Statement of *Employee #1* in support of Complaint against [redacted] D.O., Apr. 26, 2010, attachment 6, at 3.
[23] Redacted video; Statement of *Employee #4*, Nov. 23, 2012, attachment 4, at 1.
[24] 1 U.S.C. § 8(a).

whenever an infant undergoes "complete expulsion or extraction from his or her mother" and "has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion."[25] The Partial-Birth Abortion Ban Act of 2003 makes clear that such protections apply even if the infant is only partially extracted from the mother's body at the time its life is ended. Specifically, a prohibited "partial-birth abortion" occurs when a person knowingly commits "an overt act . . . that kills the partially delivered living fetus" after the fetus is partially delivered with its entire head "outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel."[26] The only exceptions occur when such a procedure "is necessary to save the life of a mother whose life is endangered" by certain categories of physical conditions.[27] Violations of the 2003 act are punishable by fines, imprisonment for up to two years, or both.[28]

The foregoing allegations advance numerous federal violations agains[redacted]—of the Partial-Birth Abortion Ban Act in those cases involving his terminations of partially delivered infants and of the Born-Alive Infants Protection Act in those cases where the infants have completely exited a mother's body. In at least the latter cases, they also amount to allegations that [redacted] violated Texas' criminal homicide statutes. First, the allegations constitute murder, defined by the Texas Penal Code as "intentionally or knowingly caus[ing] the death of an individual."[29] Second, the allegations against [redacted] constitute capital murder under Texas law in both of the following circumstances, either one of which is sufficient to establish that offense:

- "the person murders more than one person . . . during different criminal transactions but the murders are committed pursuant to the same scheme or course of conduct;"[30] and
- "the person murders an individual under 10 years of age . . . ."[31]

The murders alleged against [redacted] occurred on a repeated basis, and all occurred pursuant to his course of conduct as a provider of abortion who was alleged to have systematically killed any infant aborted while showing signs of life. The second circumstance is independently established by the obvious fact that every alleged victim was under 10 years of age.

[redacted]'s alleged conduct would also violate the gestational age limit established under Texas law. Former employees of the doctor allege he performed abortions as late as the third trimester.[32] Third trimester abortions are prohibited with narrow exceptions, inapplicable according to the allegations in the instant case, where "the abortion is necessary to prevent the death of the woman," the "unborn child has a severe, irreversible brain impairment; or . . . the woman is diagnosed with a significant likelihood of suffering imminent severe, irreversible brain

[25] 1 U.S.C. § 8(b).
[26] 18 U.S.C. § 1531(b)(1).
[27] 18 U.S.C. § 1531(a).
[28] *Id.*
[29] Tex. Penal Code § 19.02(b)(1).
[30] Tex. Penal Code § 19.03(a)(7).
[31] Tex. Penal Code § 19.03(a)(8).
[32] *Employee #1* Aff. ¶ 6; *Employee #3* Aff. ¶ 2.

damage or . . . paralysis."[33] Since H.B. 2 became effective October 29, 2013, abortions additionally have been prohibited when "the probable post-fertilization age of the unborn child is 20 or more weeks."[34] [redacted]'s abortion practice is believed to continue to the present day, so it merits investigation whether he has violated both gestational limits.

The allegations that [redacted] regularly falsified sonogram results to misrepresent the gestational age of the fetus also potentially implicate both state and federal law. Regardless of whether the patient or another entity is responsible for payment, Texas law clearly prohibits fraudulent billing. Such conduct would constitute a form of theft[35] in addition to violating Texas' prohibition on insurance fraud.[36] In those cases in which patients were eligible for Medicaid coverage, such allegations would implicate numerous federal criminal prohibitions on false statements to federal agencies[37] and on false statements involving health care benefit programs,[38] as well as the prohibitions on health care fraud.[39] Such conduct would also violate the federal False Claims Act[40] and Texas' prohibition of Medicaid fraud.[41]

Other provisions of Texas law prohibit additional conduct alleged above on the part of [redacted], including the following:

- Misrepresentation of sonogram readings: In addition to violating the above-cited statutes prohibiting fraud, tampering and altering records containing patient data is prohibited under 25 Tex. Admin. Code § 135.9(d).

- Failure to properly store and log medication: The obligation to maintain and provide drugs safely and to properly log their use is set forth in detail under 22 Tex. Admin. Code § 291.76 and made applicable to ambulatory surgical centers under 25 Tex. Admin. Code § 135.12.

- Lack of adequate medical staff: 25 Tex. Admin. Code § 135.7 requires health care practitioners to meet numerous requirements that include necessary and appropriate training and to adhere to state law and "the standards and ethics of their professions." 25

[33] Tex. Occ. Code § 164.052(a)(18). The Texas Health and Safety Code contains an additional prohibition of third-trimester abortions, under which such abortions are permitted only when they are "necessary to prevent the death or a substantial risk of serious impairment to the physical or mental health of the woman" or "the fetus has a severe and irreversible abnormality," in which case the physician is required to submit a written certification of the applicable conditions to the Department of State Health Services. Tex. Health & Safety Code §§ 170.002(b)-(c).
[34] Tex. Health & Safety Code §§ 171.044, 171.045. Exceptions apply when abortion is deemed necessary "to avert the woman's death or a serious risk of substantial and irreversible physical impairment of a major bodily function, other than a psychological condition." Tex. Health & Safety Code § 171.046. Note that these provisions of H.B. 2 were not challenged in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016).
[35] Tex. Penal Code § 31.03.
[36] Tex. Penal Code § 35.02.
[37] 18 U.S.C. § 1001; 18 U.S.C. § 287. An accompanying prohibition on conspiracy in connection with such claims is established by 18 U.S.C. § 286.
[38] 18 U.S.C. § 1035.
[39] 18 U.S.C. § 1347; 42 U.S.C. § 1320a-7b(a). If fraud is proven to have been carried out by utilizing either the mails or other applicable interstate carriers or communications, the federal mail and wire fraud statutes would also be implicated. *See* 18 U.S.C. §§ 1341, 1343.
[40] 31 U.S.C. § 3729(a)(1).
[41] Tex. Penal Code § 35A.02.

Tex. Admin. Code § 135.15 specifies requirements for an organized nursing service under the direction of a qualified registered nurse and other personnel that must be present at the medical facility. [redacted]'s former employees' allegations amount to a violation of these sections. Additional investigation is warranted into whether clinic practices were in compliance with other requirements for adequate medical staff, including 25 Tex. Admin. Code § 135.10, which addresses additional facility requirements, and 25 Tex. Admin. Code § 135.11, which addresses anesthesia and surgical services.

- Failure to observe proper sterilization procedures and disposal practices: 25 Tex. Admin. Code § 135.11(b)(12) requires the development, implementation, and enforcement of such procedures, and 25 Tex. Admin. Code § 135.52(d)(14) requires sterilizing facilities to be included and properly maintained and utilized.

- Fraudulent concealment from government authorities of the foregoing alleged violations: The fabrication, alteration, and in applicable cases concealment involved in these allegations entail conduct proscribed by Tex. Penal Code § 37.09. It also subverts the state's right to inspect facilities containing controlled substances pursuant to Tex. Health & Safety Code § 481.181.

[redacted] was previously referred to the District Attorney of Harris County, but the investigation into the matter was deficient. In light of the gravity of the allegations outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether [redacted] violated federal and state law, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225–2927

Minority (202) 225–3641

December 7, 2016

VIA EMAIL AND FIRST CLASS MAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of second- and third-trimester abortion providers and the practices of entities that procure and transfer fetal tissue. This includes investigation of partial-birth abortion and the standard of care for infants who survive the abortion procedure.

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According to several of his employees, including *Employee #1* and *Employee #2*, who were medical assistants, and *Employee #3*, who assisted with administrative tasks, numerous patients of [redacted] delivered infants alive prior to their demise, which the doctor himself brought about. Specifically, *Employee #1*, who assisted the doctor in the operating room at Aaron, estimated that "[d]uring a typical week with a full patient load, . . . [redacted] would perform

abortions at 20 or more weeks gestation, *i.e.*, later in the second trimester or in the third trimester, on approximately 40 patients."[1] Of that number, *Employee #1* asserted:

> approximately three or four infants would show signs of life. This typically happened when infants were extracted from the cervix in a breech position. At times, the infant would slide completely out because of the extent of the dilation caused by the laminaria administered to patients. In all such cases, [redacted] would terminate their lives. The signs of life they exhibited would include movement of the stomach as the infant breathed or movement of the toes or fingers.[2]

[redacted] would terminate the lives of these infants, *Employee #1* further alleges based on those incidents she witnessed, by any of several methods, including the following:

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Several of the same allegations were also made by *Employee #2*.[4]

Employee #3 was not in the treatment rooms when abortions took place, but she alleges she learned from her coworkers of numerous infants whose lives were terminated by [redacted] after showing signs of life following partial or full extraction from the uterus.[5] On one occasion, she stated that she learned from a coworker of an infant killed by the doctor after surviving an abortion; as he was preparing to put it into a bag for disposal, she maintained, the infant had "opened up his eyes and grabbed his hand."[6]

Employee #1 stated that "[o]f the three to four infants terminated in a typical week by [redacted] while showing signs of life, on average, approximately one or two would be put to death after they had left the birth canal entirely. The balance were terminated while they were partially out of the birth canal."[7] *Employee #1* added that she never observed [redacted] "make an attempt to keep alive or resuscitate any infant who showed any signs of life or to direct anyone else to do so," an observation consistent with *Employee #3*'s understanding.[8]

[1] Affidavit of *Employee #1*, Dec. 5, 2016, ¶¶ 1-2, attachment 1 [hereinafter *Employee #1* Aff.].
[2] *Id.* ¶ 3.
[3] *Id.* ¶ 4.
[4] *See* Redacted video—see key, attachment 2 [hereinafter Redacted video] ("Sometimes he would go through the stomach as well. . . . He would like force it [the instrument] through the stomach . . . and he twists it.") ("he would put, like, his finger . . . through the throat") (statements of *Employee #2*).
[5] Affidavit of *Employee #3*, Dec. 6, 2016, ¶ 2, attachment 3 [hereinafter *Employee #3* Aff.].
[6] Redacted video.
[7] *Employee #1* Aff. ¶ 5.
[8] *Id.* ¶ 5; *Employee #3* Aff. ¶ 2.

Employee #1 also alleged that '[redacted] performed numerous abortions during the third trimester in cases that did not involve any serious threats to the mother's or the infant's health."[9] *Employee #2* asserted, "As long as the patients had the cash, he was going to do it past the 25 weeks."[10] Four photographs identified by *Employee #1* and *Employee #3* as taken in the sterilization room of the Women's Pavilion in 2012 depict the remains of infants clearly in their third trimester when they were allegedly terminated by [redacted].[11] According to *Employee #1*, the tears in the neck line visible in the photos are "inconsistent with" terminations done "while the infant[s were] entirely inside the uterus."[12] Thus, besides being late-term abortions, they were likely either partial-birth abortions or homicides committed after full delivery.

Employee #1 and two other employees at the clinic, *Employee #3* and *Employee #4*, additionally allege that the doctor regularly falsified sonogram results to misrepresent the gestational age of the fetus. Some sonograms, they maintain, would be falsified to "overstate the gestational age of the fetus in order to overbill customers."[13]

In other cases, according to *Employee #1* and *Employee #3*, "sonograms would be falsified to conceal the advanced gestational age of the fetus beyond the legal limit in Texas."[14] *Employee #1* claimed:

> I have witnessed this happen in cases involving fetuses as old as 28 weeks. [redacted] would typically tell his ultrasound technician in cases involving fetuses beyond a certain gestational age to allow him to perform the ultrasound himself; he would then bring the patient an ultrasound picture showing another fetus at the gestational age he was misrepresenting to the patient.[15]

An affidavit from a patient attached hereto alleges another specific case of manipulation: *Patient #1*, a woman who obtained an abortion in 2002 at "24 to 25 weeks" gestation, "worried that I was too far along. The girl doing my ultrasound told me that 'ultrasounds can be manipulated.' The clinic determined me to be 23 weeks."[16] "On two occasions that I witnessed," *Employee #1* also alleges that '[redacted] failed to inform a patient she was pregnant with twins."[17]

According to *Employee #1* and *Employee #3*, the doctor "would regularly make use of pre-drawn medicine," including Demerol and Nubain, "without properly logging or storing it." They added:

> This included improperly storing medicine in a food refrigerator. On one occasion, [redacted] concealed these practices during an inspection from the

[9] *Employee #1* Aff. ¶ 6.
[10] Redacted video.
[11] *Employee #1* Aff. ¶ 6; *Employee #3* Aff. ¶ 3. According to *Employee #3*, the photos were taken July 26, 2012. *Id.*
[12] *Employee #1* Aff. ¶ 6.
[13] *Id.* ¶ 7; *Employee #3* Aff. ¶ 4; Statement of *Employee #4*, Nov. 23, 2012, attachment 4, at 1.
[14] *Employee #1* Aff. ¶ 7; *Employee #3* Aff. ¶ 4.
[15] *Employee #1* Aff. ¶ 7.
[16] Affidavit of *Patient #1*, June 17, 2013, attachment 5.
[17] *Employee #1* Aff. ¶ 8.

> Harris County Public Health office by having a nurse put pre-drawn medicine in basins, which she hid in the trunk of her car while the inspector was present."[18]

Employee #1 and *Employee #3* also allege the doctor failed to keep a registered nurse on site in the recovery room at Aaron, which "left unqualified workers to draw and administer drugs."[19] *Employee #1* added that [redacted] concealed this deficiency from authorities by "hir[ing] a nurse from a temp agency for a few days at a time when a government inspection was scheduled."[20] *Employee #1* recorded examples of storage, recordkeeping, and personnel violations in an undercover video from 2011 attached hereto.[21]

Additionally, according to *Employee #1*:

> [redacted] would regularly fail to observe proper sterilization procedures. This included the doctor's habitual reuse of a bottle of Betadine, which is used for cleaning prior to the procedure, that was not cleaned or stored, and which he handled with his gloved hand for patient after patient when going inside the cervix. Additionally, after removing instruments such as Hawkins-Ambler's dilators and Bierer and Sopher forceps from sterile packages, he would place unused instruments back in the sterile package to use on other patients. He often would do so wearing gloves that he did not change between seeing one patient and another, or between trips to the restroom. . . . Instruments in [redacted]'s clinic were not regularly soaked in sterilizing solutions as they needed to be for specified periods of time in order to be sterile. The exception to this occurred prior to government inspections. The vast majority of the doctor's assistants in the sterilization room were uninformed on proper methods of sterilization. In order to reduce his costs, [redacted] also habitually disposed of biohazardous waste in standard garbage bags instead of sterile bags required for such waste.[22]

The same failure with respect to sterilization was also alleged by *Employee #2*, *Employee #3*, and *Employee #4*.[23]

Violations of Applicable Laws

Federal law makes clear that infants that are born, regardless of whether naturally or by extraction during an abortion, are entitled to the same protections given to every other person. Under the Born-Alive Infants Protection Act of 2002, "every infant member of the species homo sapiens who is born alive at any stage of development" is considered a person.[24] This is so

[18] *Id.* Aff. ¶ 9; *Employee #3* Aff. ¶ 5. *See also* Redacted video.
[19] *Employee #1* Aff. ¶ 10; *Employee #3* Aff. ¶ 6.
[20] *Employee #1* Aff. ¶ 10. For additional information regarding the deficiencies in [redacted]'s nursing staff and other allegations regarding possible violations at his clinics, see Statement of *Employee #1* in support of Complaint against [redacted] D.O., Apr. 26, 2010, attachment 6.
[21] Aaron Women's Clinic video by *Employee #1*, attachment 7.
[22] *Employee #1* Aff. ¶¶ 11-12. See also Statement of *Employee #1* in support of Complaint against [redacted] D.O., Apr. 26, 2010, attachment 6, at 3.
[23] Redacted video; Statement of *Employee #4*, Nov. 23, 2012, attachment 4, at 1.
[24] 1 U.S.C. § 8(a).

whenever an infant undergoes "complete expulsion or extraction from his or her mother" and "has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion."[25] The Partial-Birth Abortion Ban Act of 2003 makes clear that such protections apply even if the infant is only partially extracted from the mother's body at the time its life is ended. Specifically, a prohibited "partial-birth abortion" occurs when a person knowingly commits "an overt act . . . that kills the partially delivered living fetus" after the fetus is partially delivered with its entire head "outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel."[26] The only exceptions occur when such a procedure "is necessary to save the life of a mother whose life is endangered" by certain categories of physical conditions.[27] Violations of the 2003 act are punishable by fines, imprisonment for up to two years, or both.[28]

The foregoing allegations advance numerous federal violations against [redacted] of the Partial-Birth Abortion Ban Act in those cases involving his terminations of partially delivered infants and of the Born-Alive Infants Protection Act in those cases where the infants have completely exited a mother's body. In at least the latter cases, they also amount to allegations that [redacted] violated Texas' criminal homicide statutes. First, the allegations constitute murder, defined by the Texas Penal Code as "intentionally or knowingly caus[ing] the death of an individual."[29] Second, the allegations against [redacted] constitute capital murder under Texas law in both of the following circumstances, either one of which is sufficient to establish that offense:

- "the person murders more than one person . . . during different criminal transactions but the murders are committed pursuant to the same scheme or course of conduct;"[30] and
- "the person murders an individual under 10 years of age . . . ."[31]

The murders alleged against [redacted] occurred on a repeated basis, and all occurred pursuant to his course of conduct as a provider of abortion who was alleged to have systematically killed any infant aborted while showing signs of life. The second circumstance is independently established by the obvious fact that every alleged victim was under 10 years of age.

[redacted]'s alleged conduct would also violate the gestational age limit established under Texas law. Former employees of the doctor allege he performed abortions as late as the third trimester.[32] Third trimester abortions are prohibited with narrow exceptions, inapplicable according to the allegations in the instant case, where "the abortion is necessary to prevent the death of the woman," the "unborn child has a severe, irreversible brain impairment; or . . . the woman is diagnosed with a significant likelihood of suffering imminent severe, irreversible brain

[25] 1 U.S.C. § 8(b).
[26] 18 U.S.C. § 1531(b)(1).
[27] 18 U.S.C. § 1531(a).
[28] *Id.*
[29] Tex. Penal Code § 19.02(b)(1).
[30] Tex. Penal Code § 19.03(a)(7).
[31] Tex. Penal Code § 19.03(a)(8).
[32] *Employee #1* Aff. ¶ 6; *Employee #3* Aff. ¶ 2.

damage or . . . paralysis."[33] Since H.B. 2 became effective October 29, 2013, abortions additionally have been prohibited when "the probable post-fertilization age of the unborn child is 20 or more weeks."[34] [redacted]'s abortion practice is believed to continue to the present day, so it merits investigation whether he has violated both gestational limits.

The allegations that [redacted] regularly falsified sonogram results to misrepresent the gestational age of the fetus also potentially implicate both state and federal law. Regardless of whether the patient or another entity is responsible for payment, Texas law clearly prohibits fraudulent billing. Such conduct would constitute a form of theft[35] in addition to violating Texas' prohibition on insurance fraud.[36] In those cases in which patients were eligible for Medicaid coverage, such allegations would implicate numerous federal criminal prohibitions on false statements to federal agencies[37] and on false statements involving health care benefit programs,[38] as well as the prohibitions on health care fraud.[39] Such conduct would also violate the federal False Claims Act[40] and Texas' prohibition of Medicaid fraud.[41]

Other provisions of Texas law prohibit additional conduct alleged above on the part of [redacted], including the following:

- Misrepresentation of sonogram readings: In addition to violating the above-cited statutes prohibiting fraud, tampering and altering records containing patient data is prohibited under 25 Tex. Admin. Code § 135.9(d).

- Failure to properly store and log medication: The obligation to maintain and provide drugs safely and to properly log their use is set forth in detail under 22 Tex. Admin. Code § 291.76 and made applicable to ambulatory surgical centers under 25 Tex. Admin. Code § 135.12.

- Lack of adequate medical staff: 25 Tex. Admin. Code § 135.7 requires health care practitioners to meet numerous requirements that include necessary and appropriate training and to adhere to state law and "the standards and ethics of their professions." 25

[33] Tex. Occ. Code § 164.052(a)(18). The Texas Health and Safety Code contains an additional prohibition of third-trimester abortions, under which such abortions are permitted only when they are "necessary to prevent the death or a substantial risk of serious impairment to the physical or mental health of the woman" or "the fetus has a severe and irreversible abnormality," in which case the physician is required to submit a written certification of the applicable conditions to the Department of State Health Services. Tex. Health & Safety Code §§ 170.002(b)-(c).
[34] Tex. Health & Safety Code §§ 171.044, 171.045. Exceptions apply when abortion is deemed necessary "to avert the woman's death or a serious risk of substantial and irreversible physical impairment of a major bodily function, other than a psychological condition." Tex. Health & Safety Code § 171.046. Note that these provisions of H.B. 2 were not challenged in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016).
[35] Tex. Penal Code § 31.03.
[36] Tex. Penal Code § 35.02.
[37] 18 U.S.C. § 1001; 18 U.S.C. § 287. An accompanying prohibition on conspiracy in connection with such claims is established by 18 U.S.C. § 286.
[38] 18 U.S.C. § 1035.
[39] 18 U.S.C. § 1347; 42 U.S.C. § 1320a-7b(a). If fraud is proven to have been carried out by utilizing either the mails or other applicable interstate carriers or communications, the federal mail and wire fraud statutes would also be implicated. *See* 18 U.S.C. §§ 1341, 1343.
[40] 31 U.S.C. § 3729(a)(1).
[41] Tex. Penal Code § 35A.02.

Tex. Admin. Code § 135.15 specifies requirements for an organized nursing service under the direction of a qualified registered nurse and other personnel that must be present at the medical facility. [redacted]'s former employees' allegations amount to a violation of these sections. Additional investigation is warranted into whether clinic practices were in compliance with other requirements for adequate medical staff, including 25 Tex. Admin. Code § 135.10, which addresses additional facility requirements, and 25 Tex. Admin. Code § 135.11, which addresses anesthesia and surgical services.

- Failure to observe proper sterilization procedures and disposal practices: 25 Tex. Admin. Code § 135.11(b)(12) requires the development, implementation, and enforcement of such procedures, and 25 Tex. Admin. Code § 135.52(d)(14) requires sterilizing facilities to be included and properly maintained and utilized.

- Fraudulent concealment from government authorities of the foregoing alleged violations: The fabrication, alteration, and in applicable cases concealment involved in these allegations entail conduct proscribed by Tex. Penal Code § 37.09. It also subverts the state's right to inspect facilities containing controlled substances pursuant to Tex. Health & Safety Code § 481.181.

[redacted] was previously referred to the District Attorney of Harris County, but the investigation into the matter was deficient. In light of the gravity of the allegations outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether [redacted] violated federal and state law, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 Rayburn House Office Building
Washington, DC 20515–6115

Majority (202) 225-2927
Minority (202) 225-3641

December 20, 2016

VIA EMAIL

The Honorable Hector H. Balderas, Jr.
Attorney General of New Mexico
408 Galisteo Street
Villagra Building
Santa Fe, NM 87501

Dear Attorney General Balderas:

On June 23, 2016, I sent you a criminal referral report pursuant to the investigation of the Select Investigative Panel (the "Panel") authorized by the U. S. House of Representatives under H. Res. 461. I now write to submit for your attention a supplementary referral concerning additional allegations regarding the University of New Mexico ("UNM") and Southwestern Women's Options ("SWWO"), the entities that were the subjects of our June referral report. This referral is based on information obtained in document productions by UNM and SWWO, deposition testimony by *Doctor #5*[1] of SWWO on May 6, 2016, and a complaint and affidavit with supporting documents submitted by a former patient at SWWO.

Allegations Against SWWO and UNM

As noted in the referral report and admitted by UNM, since 1995, SWWO has served as the only source of aborted infant tissue procured for the University of New Mexico Health and Sciences Center (UNMHSC) for research purposes.[2] From the Panel's investigation, it is apparent that there were several deficiencies in the consent process used to procure fetal tissue. Although SWWO provided the Panel a consent form that purported to give patients notice that tissue from their pregnancy would be donated to UNM,[3] there is evidence that this form was not used. While

[1] Names in this letter are redacted with the same pseudonyms used in the June 23 letter. *See* redaction key.
[2] UNM Document, UNM00560, attachment 1; UNM First Submission to House Select Panel, Jan. 29, 2016, p. 1, attachment 2; UNM Second Submission to House Select Panel, Feb. 16, 2016, p. 1, attachment 3; UNM Response to House Select Panel Subpoena, Mar. 3, 2016, p.1, attachment 4.
[3] Client Information for Informed Consent, Donation of Fetal Tissue for Medical Research, SWWO000524, attachment 5.

Doctor #5 testified that SWWO's practice was to provide women an opportunity to donate the tissue that resulted from their abortions and to obtain their consent to do so, she admitted she had never gotten a consent from a patient at SWWO to make a fetal tissue donation—and did not even recognize the consent form that SWWO produced to the Panel.[4] She also admitted she was unaware of whether consent was required prior to the donation of fetal tissue.[5]

Further evidence supports the inference that patients were not regularly given a fetal tissue donation consent form at SWWO. *Patient*, a patient who obtained an abortion from SWWO, has brought suit against the clinic and attested in an affidavit that she was never given a "consent to donate tissue that was separate from the consent for the [abortion] procedure."[6] Moreover, she alleges she was never informed by the doctors and staff at SWWO that her infant's remains were to be donated to UNM or another entity.[7] Neither, she alleged, was she informed of the nature and extent of any use of such remains, "which body parts were going to be used or donated," or what benefits could be expected from such use.[8] She added that she was not informed by SWWO doctors or staff that the doctor who treated her, *Doctor #6*, and the director of SWWO, *Doctor #3*, were volunteer faculty members at UNM, or that the clinic and the university had been collaborating on fetal tissue research since 1995.[9]

Even more problematically, the only semblance of consent SWWO allegedly sought from *Patient* for fetal tissue research was a phrase mentioning the use of "tissue and parts . . . in medical research" within a two-page consent form provided to her for the abortion procedure itself.[10] Thus, the only consent sought from her for fetal tissue donation came during what should have been a separate process of consent to the abortion procedure itself. A letter from *Patient* to SWWO dated December 2, 2015, requested "all information regarding the disposal, donation or sale of any medical waste," but she allegedly never received any records regarding the disposition of her infant's remains.[11] In September 2016, *Patient* read procurement notes dated October 17, 2012, that were attached to the Panel's referral of UNM and SWWO to the Attorney General of New Mexico that indicated brain tissue had been taken from one infant estimated at 11.5 weeks gestation and another at 12.7 weeks gestation.[12] Because *Patient's* ultrasound taken on October 5, 2012, stated she was 12 weeks and two days pregnant, and because she obtained her abortion five days later on October 10—when staff informed her she was between 12 and 13 weeks pregnant—she believed her "baby was one of the two babies given to the University of

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[4] Transcript of Deposition of *Doctor #5*, May 6, 2016 ("*Doctor #5* Tr.") at 162-63, 165-67, 188-89, 212-13. The consent form itself was marked twice during *Doctor #5*deposition, as Ex. 6 without a Bates number and as Ex. 12 with Bates number SWWO000524, the version the clinic produced to the Panel. *Id.* at 164-65, 212-13. *Doctor #5* maintained it was the job of a counselor rather than a doctor to obtain a consent. *Id.* at 190.

[5] *Doctor #5* Tr. at 273.

[6] Affidavit of *Patient*, Nov. 18, 2016 ("*Patient* Aff."), ¶ 30, attachment 6. *See also* Complaint ¶ 47, *Patient* v. *Doctor #3*, No. D-202-CV-2016-07498 (N.M. Dis. Ct. Bernalillo County Nov. 30, 2016) ("*Patient* Compl."), attachment 7. In an email dated Nov. 28, 2016, *Patient* gave permission to the Panel to disclose her identity publicly, but the Panel decided nonetheless to redact her name in the instant letter.

[7] *Patient* Aff. ¶ 10; *Patient* Compl. ¶ 32.

[8] *Patient* Aff. ¶¶ 21-22, 26; *Patient* Compl. ¶¶ 35-38.

[9] *Patient* Aff. ¶¶ 15, 18-20; *Patient* Compl. ¶ 32.

[10] *Patient* Aff. ¶ 8 & Ex. A, at 1; *Patient* Compl. ¶¶ 11-12 & Ex. A.

[11] *Patient* Aff. ¶¶ 32-33 & Ex. B; *Patient* Compl. ¶¶ 54-57.

[12] Compare *Patient* Aff. ¶¶ 35-36 and Procurement Notes, UNM00029. *See also Patient* Compl. ¶ 52.

New Mexico for their research."[13] This belief is consistent with SWWO's practice of storing fetal tissue in an on-site freezer until it is periodically picked up for transfer to UNM.[14] *Patient* attested, "If I had known my baby was going to be used for research I would have probably changed my mind about going through with the abortion," and added that the actions of SWWO and its doctors caused her "emotional distress and mental anguish."[15] *Patient* additionally alleged that she was advised by staff that she could apply for Medicaid funding for her abortion procedure and that the paperwork supporting such funding was prepared by a doctor she never saw, *Doctor #7*, and not her treating physician, *Doctor #6*.[16]

Violations of Applicable Laws

If true, *Patient's* allegation that the only informed consent to tissue donation sought from her was the cursory reference to the use of "tissue and parts . . . in medical research" in SWWO's abortion consent form amounts to violations of federal and state law by UNM and SWWO.

HHS regulations, which govern much of the human subject research conducted at UNM, requires in 45 C.F.R. § 46.116 a number of basic elements of informed consent:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
>
> (2) A description of any reasonably foreseeable risks or discomforts to the subject;
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
>
> (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
>
> (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
>
> (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

[13] *Patient* Aff. ¶¶ 7, 12-13, 37-38; *Patient* Compl. ¶¶ 49-53.
[14] SWWO letter responding to document request (Feb. 12, 2016), at 5; *Doctor #5* Tr. at 182-85. According to SWWO's Feb. 12 letter, pickup occurred weekly, but procurement notes record that pickup occurred an average of 39 times per year since 2010, 45 times in 2012.
[15] *Paitnet* Aff. ¶¶ 39, 42; *Patient* Compl. ¶¶ 60, 142.
[16] *Patient* Aff. ¶¶ 14-17; *Patient* Compl. ¶¶ 61-64, 110.

> (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
>
> (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.[17]

According to *Patient's* allegations, both SWWO and UNM failed to provide any of these elements of informed consent, in violation of 45 C.F.R. § 46.116, accompanied by a violation of 45 C.F.R. § 46.117 for failing to present such consent in writing.

To the extent the research of the fetal tissue acquired by UNM related to transplantation for therapeutic purposes, any violations by SWWO and UNM would include violation of 42 U.S.C. § 289g-1(b)(1), which requires written consent from the woman acknowledging the nature of the research, the lack of "restriction regarding the identity of individuals who may be the recipients of transplantation of the tissue," and that the woman was not informed of any such recipients' identities. Moreover, the use of a consent form that simultaneously seeks consent for abortion and for fetal tissue donation under the alleged circumstances would appear to violate 42 U.S.C. § 289g-1(b)(2)(A)(i), which requires the abortion consent to be "obtained prior to requesting or obtaining consent for a donation of the tissue . . . ."

UNM's own oversight policy provided as of 2015 that "appropriate informed consent by the mother" is required for "[t]he collection and storage of all fetal tissue for research."[18] The policy as revised April 11, 2016, further clarifies that UNMHSC

> will not acquire such fetal tissue from outside entities (a) without contractual and/or written assurance that the fetal tissue being acquired was collected in accordance with a process that separates the informed consent for the abortion procedure from the informed consent to donate such fetal tissue to the UNM HSC for Research, and (b) where there is contractual assurance that the terms of the acquisition complies fully with Section 112(a) of the NIH Act (42 U.S.C. § 289g-2(a)). In addition, the contractual assurance contemplated in Subsection 2 must indicate that there are no legal, ethical, or other restrictions against transferring the Research Tissues to the UNM HSC, nor against the UNM HSC's use of them.[19]

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[17] 45 C.F.R. § 46.116(a). These elements are the minimum required, subject to exceptions for public benefit or service programs under § 46.116(c) and potentially additional requirements under § 46.116(b).

[18] UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP (Sept. 16, 2015), UNM03420-UNM03428 at UNM03423.

[19] UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP (Apr. 11, 2016), at 3. This revised policy additionally reinforces the Panel's June 23, 2016, referral regarding violation of the Spradling Act by

UNM did not produce this revised policy to the Panel.

Despite SWWO's inclusion of a fetal tissue donation consent form in its production, *Patient's* allegation that it was never shown to her, combined with *Doctor #5* admission that she did not even recognize the form, raises a serious question as to whether SWWO and UNM systematically violated the law, not to mention UNM's own internal policy, by conducting fetal tissue donations without more than the perfunctory reference to tissue research in SWWO's abortion consent form.

The same alleged deficiencies in the consent process at SWWO would constitute a violation of New Mexico's state law. Regardless of whether government funding or transplantation research is involved, N.M. Stat. Ann. § 24-9A-5, which is part of the Maternal, Fetal and Infant Experimentation Act, prohibits any "clinical research activity involving fetuses, live-born infants or pregnant women" unless the woman

> has been fully informed of the following:
>
> (1) a fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental;
> (2) a description of any attendant discomforts and risks reasonably to be expected;
> (3) a description of any benefits reasonably to be expected;
> (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
> (5) an offer to answer any inquiries concerning the procedure; and
> (6) an instruction that the person who gave the consent is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.[20]

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requiring that fetal tissue for research be acquired "in accordance with the provisions of the" Spradling Act "and/or with contractual assurance that it was obtained in accordance with" that statute. *Id.* at 3-4.

[20] N.M. Stat. Ann. § 24-9A-5(C). As discussed above, the Spradling Act prohibits use of fetal tissue resulting from induced abortion, but this informed consent provision provides a basis for liability separate from the underlying use of such tissue. It additionally should be noted that the Maternal, Fetal and Infant Experimentation Act defines the term "clinical research" as follows:

> "clinical research" means any biomedical or behavioral research involving human subjects, including the unborn, conducted according to a formal procedure. The term is to be construed liberally to embrace research concerning all physiological processes in human beings and includes research involving human in vitro fertilization, but shall not include diagnostic testing, treatment, therapy or related procedures conducted by formal protocols deemed necessary for the care of the particular patient upon whom such activity is performed and shall not include human in vitro fertilization performed to treat infertility; provided that this procedure shall include provisions to ensure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient, and no physician may stipulate that a woman must abort in the event the pregnancy should produce a child with a disability. Provided that emergency medical procedures necessary to

This statute is notably cited in the standard operating procedures of UNM's Office of the Institutional Review Board, but UNM failed to produce that document to the Panel.[21] Other sections of the Maternal, Fetal and Infant Experimentation Act make clear that neither a pregnant woman nor a fetus shall be involved as subjects in clinical research activity unless "the mother is legally competent and has given her informed consent,"[22] subject to penalties of imprisonment for less than one year and/or payment of a fine up to $1,000.[23]

I urge your office to conduct a thorough investigation into whether the University of New Mexico and Southwestern Women's Options violated federal and state law, and, if you conclude that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chairman
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

The Honorable Susana Martinez
Governor of New Mexico

The Honorable John A. Sanchez
Lieutenant Governor of New Mexico

The Honorable Steve Pearce
Second Congressional District, New Mexico

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preserve the life or health of the mother or the fetus shall not be considered to be clinical research . . . ."

N.M. Stat. Ann. § 24-9A-1(D).

[21] See UNM Office of the Institutional Review Board, Standard Operating Procedures, effective Mar. 1, 2016, at 1-2, http://irb.unm.edu/sites/default/files/511.0%20Compliance%20with%20Applicable%20Laws%20and%20Regulations.pdf, attachment 8.

[22] N.M. Stat. Ann. §§ 24-9A-2(B), 24-9A-3(B).

[23] N.M. Stat. Ann. § 24-9A-6.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

December 20, 2016

VIA EMAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

The Panel investigation discovered information that StemExpress, LLC ("StemExpress"), a firm that procures fetal tissue from abortion clinics and transfers it to research customers, may have destroyed documents in violation of Title 18 U.S.C. § 1519. The transfer of fetal tissue for valuable consideration is a matter within the jurisdiction of the United States. Specifically, Title 42 U.S.C. § 289 (g) makes it a felony to receive valuable consideration for fetal tissue in excess of allowable costs.

From July 16, 2015 through the passage of H. Res. 461, the Senate Committee on the Judiciary ("Senate Judiciary"), the House Committee on Energy and Commerce ("Energy and Commerce"), and the House Committee on Oversight and Government Reform ("OGR") all conducted inquiries into the fetal tissue industry. The Senate Committee on the Judiciary's investigation still continues. During the course of those congressional inquiries, all of those committees sent document request letters to StemExpress.

Under 18 U.S.C. § 1519, "Whoever knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the

jurisdiction of any department or agency of the United States"[1] commits a felony that is punishable by imprisonment for up to 20 years.[2]

The Panel has discovered a regime of StemExpress' potential destruction of documents that were the subject of congressional inquiries, document request letters, and subpoenas. This regime, which dates back to August 2015 and continues through the present, involves StemExpress' retention of a company that shreds documents for clients, and the production of accounting records that were created by StemExpress' counsel, which the counsel represented were produced by StemExpress itself.

A. Destruction of Documents

Senate Judiciary Committee

On July 16, 2015, Senate Judiciary sent StemExpress a document request letter for all records relating to StemExpress' communications with a senior official of Planned Parenthood, and with Planned Parenthood itself that related to "the centralization or coordination of StemExpress' acquisition of fetal tissue from Planned Parenthood's individual affiliates . . ."[3] On July 24, 2015, StemExpress produced only copies of its contract with Planned Parenthood affiliates.[4]

On August 13, 2015, StemExpress made its first payment to Shred-It-USA.[5] StemExpress bank records dating back to November 2012 reveal there were no payments made to Shred-It USA before August 13, 2015.[6] On August 19, 2016, StemExpress made a second production to Senate Judiciary.[7]

On August 25, 2015, StemExpress made its second payment to Shred-It-USA.[8] On September 17, 2015, Senate Judiciary sent its second document request letter to StemExpress.[9] On September 17, 2015, StemExpress produced documents to Senate Judiciary.[10] On September 24,

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[1] 18 U.S.C. § 1519.
[2] 18 U.S.C. § 1519.
[3] Letter from Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, to [redacted] Founder and CEO, Stem Express, (Jul. 16, 2015), at 2.
[4] *See* Letter from Stephen M. Ryan, McDermott Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Response to Senate Judiciary Committee's July 16, 2015 Request for Information, (Jul. 24, 2015).
[5] Panel analysis of Five Star Bancorp production to Select Investigative Panel.
[6] Five Star Bank Production [5 Star 000001 – 5 Star 000511].
[7] *See* Letter from Stephen M. Ryan, McDermott Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Second Response to Senate Judiciary Committee's July 16, 2015 Request for Information, (Aug. 19, 2015).
[8] Panel analysis of Five Star Bancorp production to Select Investigative Panel.
[9] *See* Letter from Stephen M. Ryan, McDermott, Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Second Response to Senate Judiciary Committee's September 17, 2015 Request for Information, (Oct. 28, 2015). ("I am writing today on behalf of my client, StemExpress, in regard to the letter you sent to the company on September 17, seeking information related to StemExpress; 'acquisition and transfer of fetal tissue.'").
[10] Letter from Stephen M. Ryan, McDermott, Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Second Response to Senate Judiciary Committee's September 17,

2015, StemExpress produced documents to Senate Judiciary.[11] On September 29, 2015, StemExpress made a payment to Shred-It-USA.[12] On October 28, 2015, StemExpress produced documents to Senate Judiciary.[13]

Energy and Commerce

On August 7, 2015, Energy and Commerce sent a letter to StemExpress that requested a briefing related to StemExpress' procurement, sale and donation of fetal tissue.[14] On August 13, 2015, StemExpress made its first payment to Shred-It-USA.[15] On August 21, 2015, StemExpress produced documents to Energy and Commerce.[16]

The briefing between StemExpress and Energy and Commerce staff was held on August 25, 2015. On August 24, 2015 StemExpress voluntarily produced documents to Energy and Commerce.[17] Congressional staff requested additional information and documents from StemExpress.[18] On August 25, 2015, StemExpress made its second payment to Shred-It-USA.[19] On September 11, 2015 StemExpress produced documents pursuant to the requests from the Majority and Minority.[20]

2015 Request for Information, (Oct. 28, 2015). ("StemExpress made an initial production in response to the September 17 letter shortly after receipt . . .").

[11] Letter from Stephen M. Ryan, McDermott Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress First Response to Senate Judiciary Committee's September 17, 2015 Request for Information, (Sep. 24, 2015).

[12] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[13] Letter from Stephen M. Ryan, McDermott, Will & Emery, to Sen. Charles E. Grassley, Chairman, Senate Committee on the Judiciary, Re: StemExpress Second Response to Senate Judiciary Committee's September 17, 2015 Request for Information, (Oct. 28, 2015).

[14] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Fred Upton, Chairman, House Energy & Commerce Committee, Re: StemExpress Response to House Energy and Commerce Committee's August 7, 2015 Request for a Briefing, (Aug. 21, 2015), at 1. ("I am writing today on behalf of my client, StemExpress, in regard to the letter you sent to the company on August 7, 2015, seeking a briefing related to StemExpress's 'practices regarding human fetal tissue collection, sale and/or donation.'").

[15] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[16] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep, Fred Upton, Chairman, House Energy & Commerce Committee Re: StemExpress Response to House Energy and Commerce Committee's August 7, 2015 Request for a Briefing, (Aug. 21, 2015).

[17] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Fred Upton, Chairman, House Energy & Commerce Committee, Re: StemExpress Response to House Energy and Commerce Committee's August 7, 2015 Request for a Briefing, (Aug. 24, 2015), at 1. ("In advance of our voluntary briefing to staff scheduled for August 25, we are voluntarily responding to the staff's request by producing several documents to facilitate our discussion.").

[18] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Fred Upton, Chairman, House Energy & Commerce Committee, (Sep. 11, 2015), at 1. ("As you know, StemExpress's CEO, [redacted] voluntarily agreed to provide a briefing to the Committee's staff on August 25. Following this briefing, both the Majority and Minority staff provided StemExpress with a list of 20 additional request.").

[19] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[20] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Fred Upton, Chairman, House Energy & Commerce Committee, Re: StemExpress Third Response to House Energy and Commerce Committee's August 7, 2015 Request for a Briefing (Follow-Up Requests), (Sep. 11, 2015), at 1.

OGR

On September 9, 2015, OGR sent a document request letter to StemExpress.[21] StemExpress produced documents to OGR on September 2, 2015 and September 23, 2015.[22] On September 29, 2015, StemExpress made a payment to Shred-It-USA.[23] On October 9, 2015, StemExpress produced more documents to OGR.[24]

The Panel

The Panel was created on October 7, 2016. On November 10, 2015 StemExpress made a payment to Shred-It-USA.[25] On December 10, 2015, StemExpress made another payment to Shred-It-USA.[26] During that time period, StemExpress was under investigation by Senate Judiciary and OGR.

On December 17, 2015, the Panel sent StemExpress a document request letter.[27] On December 18, 2015, congressional staff had a telephone conference with counsel for StemExpress to discuss the document request. On December 22, 2015, StemExpress produced documents to the Panel.[28]

On January 12, 2015, StemExpress made a payment to Shred-It-USA.[29] On January 15, 2015, StemExpress produced documents to the Panel.[30] On January 27, 2015, StemExpress made a

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[21] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Jason Chafettz, Chairman, House Committee on Oversight and Government Reform, Re: StemExpress First Response to House Committee on Oversight and Government Reform's September 9, 2015 Request for Information, (Sep. 23, 2015), at 1. ("I am writing today on behalf of my client, StemExpress, in regard to the letter you sent to the company on September 9, 2015, seeking documents and information regarding 'the process whereby StemExpress obtained fetal tissue from Planned Parenthood Federation of America . . .'").

[22] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Jason Chafettz, Chairman, House Committee on Oversight and Government Reform, Re: StemExpress First Response to House Committee on Oversight and Government Reform's September 9, 2015 Request for Information, (Sep. 23, 2015), at 1. ("As an initial matter, StemExpress voluntarily produced several documents to the Committee's staff on September 2, 2015. Accordingly, today's production represents StemExpress's second voluntary response to the Committee's inquiries . . .").

[23] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[24] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Jason Chaffetz, Chairman, House Committee on Oversight and Government Reform, Re: StemExpress Second Response to House Committee on Oversight and Government Reform's September 9, 2015 Request for Information, (Oct. 9, 2015).

[25] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[26] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[27] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [redacted] Founder and CEO, StemExpress, LLC (Dec. 17, 2015). The letter sought, among other items, asking for, among other items, a list of all entities from which it procured fetal tissue, a list of all entities to which it sold or donated fetal tissue, an organization chart, all communications that direct its employees to procure fetal tissue, a list of all federal funds the firm received, accounting records, and all StemExpress banking records related to the procurement, sale, donation, or distribution or shipment of fetal tissue.

[28] Letter from Stephen M. Ryan, McDermott Will & Emery, to Rep. Marsha Blackburn, Chair, Select Panel on Infant Lives , Re: StemExpress Response to House "Select Panel on Infant Lives" December 17, 2015 Request for Documents, (Dec. 22, 2015).

[29] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[30] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Marshal Blackburn, Chair, Select Panel on Infant Lives, Re: StemExpress LLC Second Production in Response to House "Select Panel on Infant Lives" December 17, 2015 Request for Documents, (Jan. 15, 2016).

payment to Shred-It-USA.[31] On February 1, 2016, StemExpress produced documents to the Panel.[32]

On February 12, 2016, the Panel issued a subpoena to StemExpress.[33] The subpoena to StemExpress instructed that: "No records, documents, data or information called for by this

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[31] Panel analysis of Five Star Bancorp production to Select Investigative Panel.
[32] Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Marsha Blackburn, Chair, Select Panel on Infant Lives, Re: StemExpress LLC Third Production to House "Select Panel on Infant Lives" December 17, 2015 Request for Documents, (Feb. 1, 2016).
[33] Subpoena to StemExpress, LLC, (Feb. 12, 2016). The subpoena demanded the following:

> 1) Documents sufficient to show (a) all entities from which StemExpress procured fetal tissue, and (b) all entities to which StemExpress transported, sold, donated, moved, or shipped fetal tissue. Should StemExpress wish to produce a list of such entities referenced in (a) and (b) in lieu of documents, it may do so.
>
> 2) Documents sufficient to show the name and title of all StemExpress current and former employees whose responsibilities included procuring, researching, storing, packaging for donation, sale, transport, or disposal of fetal tissue, and the identity, of any supervisory personnel under whom such individuals worked.
>
> 3) All communications and documents relating to StemExpress employee compensation resulting from or relating to fetal tissue samples procured by current and former StemExpress personnel or other persons or entities that transact business with StemExpress.
>
> 4) All communications and documents that identify any federal, state, or local government funds received, directly or indirectly, by StemExpress.
>
> 5) All communications referring or relating to abortion or fetal tissue between StemExpress and any federal, state, or local government officials or employees.
>
> 6) All communications and documents regarding any direction to StemExpress current or former personnel with respect to the procurement or disposal of fetal tissue.
>
> 7) All communications and documents that StemExpress utilizes to obtain patient consent for fetal tissue at any clinic.
>
> . . . 8) All communications and documents, including but not limited to accounting memoranda, referring or relating to the cost and pricing of fetal tissue by StemExpress.
>
> 9) All communications and documents, sorted by customer, referring or relating to requests or orders made to StemExpress regarding fetal tissue and the amount paid by each customer to StemExpress.
>
> 10) All communications and documents referring or relating to the purchase, ownership, or rental by StemExpress of equipment for the storage, disposal, modification, or research of fetal tissue, including equipment price, purchase date, maintenance costs, and records of the depreciation treatment under the tax code of any such equipment.
>
> 11) All StemExpress banking and accounting documents, sorted by any source of fetal tissue and any customer of StemExpress, that reflect accounts payable and/or funds received that in any way refer or relate to the procurement, sale, donation, or distribution or shipment of fetal tissue.

request shall be destroyed, modified, removed, transferred or otherwise made inaccessible to the Select Panel."[34] On March 21, 2016, StemExpress made a payment to Shred-It-USA.[35] On March 28, 2016, StemExpress produced documents to the Panel pursuant to the subpoena.[36]

On April 26, 2015, StemExpress made a payment to Shred-It-USA.[37] On May 10, 2016, StemExpress produced documents to the Panel pursuant to the February 2016 subpoena.[38]

b. Intent to Obstruct

Documents produced to Congress and testimony before congressional inquiries strongly suggest StemExpress' intent to potentially subvert congressional investigations. The investigations involve matters within the jurisdiction of the United States. An attempt to obstruct such an investigation would violate Title 18 § 1519.

In productions to Senate Judiciary, OGR, and the Panel, StemExpress refused to provide congress with a list of all the entities from which it obtained fetal tissue.[39] StemExpress refused to produce to the Panel requested accounting documents, StemExpress represented that it had lost money on fetal tissue procured from Planned Parenthood affiliates.[40]

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12) Documents sufficient to show any known litigation in which StemExpress is named as a party, including any threatened or anticipated litigation. Should StemExpress wish to produce a list of such litigation, including appropriate docket information, in lieu of documents, it may do so.

Subpoena to StemExpress, LLC (Feb. 12, 2016) (Schedule).

[34] Subpoena to StemExpress, LLC, at Instruction Item 5, (Feb. 12, 2016).

[35] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[36] Letter to Rep. Marsha Blackburn, Chair, Select Panel on Infant Lives, Re: Fourth Production in Response to February 12, 2016 subpoena Issued to StemExpress LLC, (Mar. 28, 2016).

[37] Panel analysis of Five Star Bancorp production to Select Investigative Panel.

[38] StemExpress Sixth Response to House Select Panel Subpoena Produced on May 10, 2016. [STEM.HOUSE.SELECT_0908 – STEM.HOUSE.SELECT_0913].

[39] *See* StemExpress Second Response to Senate Judiciary Committee September 17 Letter, undated. ("StemExpress has obtained fetal tissue from two Planned Parenthood affiliates . . . . StemExpress has also obtained fetal tissue from five independent (non-Planned Parenthood) clinics. StemExpress agrees to identify the states where it has agreements with independent clinics, but will not be providing the names of these clinics . . ."). [STEM.JUD000000024; STEM.HOUSE.SELECT_0057]. StemExpress Response to House Committee on Oversight and Government Reform, (Dec. 22, 2015). ("StemExpress has obtained fetal tissue from two Planned Parenthood affiliates . . . and from independent (non-Planned Parenthood) clinics. StemExpress agrees to identify the states where it has agreements with independent clinics, but will not be providing the names of these clinics . . .") [STEM.HOUSE.ORG_000018 / STEM.HOUSE.SELECT_0184]. StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016), at 2. (". . . many of the company's contracts are subject to non-disclosure agreements and, therefore, cannot be voluntarily produced.") [STEM.HOUSE.SELECT_0228].

[40] StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016), at 6. (". . . unaltered fetal tissue procured from Planned Parenthood affiliates generated approximately $50,000 in gross (pre-tax) revenue against expenses in excess of $75,000. StemExpress charged researchers a fee of roughly $500 to $600 for unaltered tissues, but incurred directly associated expenses of approximately $750 to $1,000 for each procurement. Other costs included compensation paid to StemExpress' tissue procurement personnel and costs associated with training, packaging and ordering supplies, overnight shipping charges, infectious disease screening. . ."). [STEM.HOUSE.SELECT_0232]. StemExpress invoices produced to the Panel show that StemExpress charged its customers the costs of infectious disease screening, overnight shipping charges, and some supplies. Those charges cannot have been incurred by both StemExpress and its customers.

In response to the Panel's February 12, 2016, subpoena StemExpress produced communications that spanned only two years instead of the five required by the subpoena and these were so replete with redactions as to render them unusable.[41] StemExpress produced only "roll-up" accounting summaries, not the required primary source accounting records.[42]

In response to Specification 4, which required the production of communications and documents that identify any federal, state, or local government funds received, directly or indirectly, by the firm, StemExpress responded that it had nothing responsive to produce. ("StemExpress has confirmed that there are no communications or documents responsive to this . . ."). [43] Despite that representation, the Panel discovered that StemExpress received more than $9,000 in a small business loan from the U.S. Small Business Administration.[44]

[redacted] refused to produce any documents to the Congress pursuant to the Panel's March 29, 2016 subpoena to her.[45] [redacted] supplied the name of the Scinto Group, LLP ("Scinto"), an outside accounting firm that provided services to StemExpress, and suggested that the Panel seek the information it required from Scinto or from [redacted] a former employee of StemExpress. [46] Attorneys for [redacted] offered summary documents of revenue and costs but no accounting records.[47]

[redacted] offer of [redacted] as a source of accounting records proved hollow. [redacted] and StemExpress' counsel, who also represented former employee [redacted] explained that [redacted] had only W-2's and related tax information. In a teleconference with Congressional staff, [redacted] stated that she had no documents and that if the Panel contacted her again she would call the police.[48]

On April 29, 2016, the Panel issued a subpoena to Scinto.[49] Scinto refused to comply with the Panel's subpoena and produced no documents. Scinto told the Panel that StemExpress objected

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[41] [41] *See* StemExpress, Third Response to House Select Investigative Panel Subpoena, Apr. 11, 2016. [STEM.HOUSE.SELECT_0667].
[42] *See* Letter from Amandeep S. Sidhu, McDermott Will & Emery, to T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel (Mar. 18, 2016), at 1; Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Blackburn, Chairman, House Select Investigative Panel (May 6, 2016), at 2.
[43] *See* StemExpress, Third Response to House Select Investigative Panel Subpoena, Apr. 11, 2016. [STEM.HOUSE.SELECT_0667].
[44] Center for Effective Government website, www.FedSpending.org.
[45] "StemExpress First Response to House Select Panel's March 29, 2016 Subpoena," at 2-3.
[46] "StemExpress First Response to House Select Panel's March 29, 2016 Subpoena," at 2-3.
[47] "StemExpress First Response to House Select Panel's March 29, 2016 Subpoena," at 1-2.
[48] Memorandum from House Select Investigative Panel Counsel to Majority Members of the House Select Investigative Panel, Mar. 7, 2016.
[49] Subpoena to Scinto Group, LLP, (Apr. 29, 2016). The subpoena required the production of:

> 1) All communications and documents referring or relating to StemExpress, LLC, or StemExpress Foundation (collectively known as "StemExpress").
>
> 2) Documents sufficient to show all institutions or entities to which StemExpress donated or provided fetal tissues for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

to Scinto's compliance with the Panel's subpoena on the grounds of several privileges.[50] The Panel informed Scinto its objections based upon the asserted privileges, were inapplicable and do

. . . 3) Copies of all invoices (by month and year), reflecting the billing that StemExpress issued to all institutions or entities to which StemExpress donated or provided fetal tissues for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

4) Documents sufficient to show all institutions or entities from which StemExpress obtained fetal tissues for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

. . . 5) Copies of all invoices (by month and year) reflecting the billing or payment of funds for fetal tissues obtained by StemExpress for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

6) A copy of any chart of accounts for StemExpress, including but not limited to account descriptions from any financial recording system relating to StemExpress.

7) StemExpress' end of year trial balance report and trial balance details for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

8) All documents reflecting StemExpress' statement of revenues (i.e., a breakdown by product categories) for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

9) All documents reflecting StemExpress' record of costs and expenses (i.e., a breakdown by operations, including fetal tissue acquisition) for administrative costs and expenses as well as compensation and benefits, for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Where applicable, records should include identification of vendors and descriptions of expenses.

10) StemExpress' balance sheets for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Audited statements should be provided, if available.

11) StemExpress' income statements, including but not limited to any profit and loss statements, statements of operations and statements of activities for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Audited statements should be provided, if available.

12) Copies of Stem Express' filed tax returns for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

13) All StemExpress bank statements from any financial institution where StemExpress has maintained an account for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

14) Documents sufficient to show how StemExpress calculates the cost of a fetal tissue and all factors applied in determining pricing of fetal tissue. In lieu of these documents, you may provide a written explanation.

15) Documents sufficient to show StemExpress' cost of production and revenue from the following products: CD34+StemlProgenitor Cells; CD36+ Erythroid Progenitor; CD 133+ Stem/ Progenitor Cells; Fetal Fiver Mononuclear Cells. (Schedule).

[50] *See* email from Kevin Murphy, counsel for Scinto Group LLP, to House Select Investigative Congressional staff (Jun. 15, 2016) ("StemExpress has now told me definitively that it does not waive any available and applicable privileges or confidentiality rights in regard to the records related to StemExpress that are in the possession of my client, Scinto, and that StemExpress holds Scinto accountable to observe and protect those privileges and confidentiality rights. As you know, because Scinto is a CPA firm and tax preparer for StemExpress, there are potentially applicable privileges and confidentiality statutes, under the Internal Revenue Code and related provisions, under the California Business & Professions Code and Tax Code, and under professional standards. I understand that you probably do not agree that any of those laws or provisions would ultimately be found by a court to be applicable, but from our reading of the laws and provisions, we believe that the privilege and confidentiality

not impair the legal requirement to comply with a congressional subpoena.[51] Despite these efforts, Scinto refused to comply with this Panel's subpoena.[52]

In documents produced by an entity from which StemExpress procured fetal tissue, the Panel discovered that StemExpress had an account at Five Star Bancorp. On April 29, 2016, the Panel issued a subpoena to Five Star Bancorp. [53] During a telephone conference with congressional staff, counsel for Five Star Bancorp stated that StemExpress had threatened litigation against his client if it complied with the Panel's subpoena.[54]

On August 23, 2016, the Panel was informed by McDermott Will & Emery, the law firm previously representing StemExpress and [redacted] throughout the course of the investigation, that StemExpress was no longer their client.[55] StemExpress' former attorney supplied the Panel with contact information for the new lawyer.[56] On September 8, 2016, Chairman Blackburn sent a letter to Mr. Frank Radoslovich, the new counsel for StemExpress and [redacted] outlining a

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laws/provisions could be found applicable. I have also reviewed correspondence and a memorandum from the Democratic members of the Select Investigative Panel which assert that the subpoena (and others) was issued in violation of House rules. I have also reviewed articles (including the comprehensive articles by the Congressional Research Service) and court cases regarding enforcement of subpoenas from a House committee or subcommittee or investigative committee. My conclusion, based upon a reading of all these materials, and in light of the position conveyed to me by StemExpress, is that Scinto has an obligation to object to the subpoena.").

[51] *See* T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel, to Kevin Murphy, counsel for Scinto Group, LLP (Sept. 8, 2016).

[52] *See* Letter from Kevin Murphy, counsel for Scinto Group, LLP, to T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel (Sept. 16, 2016) ("First, let me reiterate that, if not for the potential application of the privilege and/or confidentiality laws, Scinto Group LLP would be willing and able to comply with a valid subpoena from the Select Investigative Panel. However, in light of the potential application of those laws, under the current circumstances, Scinto Group is not in a position to unilaterally respond to the subpoena with the requested documents, absent client consent.").

[53] *See* Subpoena to Five Star Bancorp (Apr. 29, 2016). that required the production of:

> For the period January 1, 2010, through the present, all documents relating to any Five Star Bank account(s) held by or in the name of Stem Express, LLC, and all documents relating in any way to account number 0032068931.
>
> This request encompasses, but is not limited to, all:
>
> 1) Monthly account statements;
>
> 2) Credit card transaction receipts;
>
> 3) Documents reflecting payments related to the account(s), including, but not limited to, checks (front and back), debit memos, cash in tickets, and wire transfers; and
>
> 4) Correspondence related to the account(s).

(Schedule).

[54] Telephone conference between David R. Gabor, Weintraub Tobin Chediak Coleman Grodin, and congressional staff (May 26, 2016).

[55] Email from Amandeep S. Sidhu, McDermott Will & Emery, to House Select Investigative Panel staff (Aug. 23, 2016).

[56] Email from Amandeep S. Sidhu, McDermott Will & Emery, to House Select Investigative Panel staff (Aug. 23, 2016).

brief history of the Panel's interactions with StemExpress, and the Panel's unsuccessful attempts to reach an accommodation with StemExpress.[57] The letter concluded:

> Since StemExpress has been unwilling to comply with the Panel's subpoenas and having exhausted all its efforts to obtain compliance from the subpoena recipients, the Chairman of the Select Investigative Panel will recommend that StemExpress and [redacted] be held in contempt for their willful failure to fully comply with the Panel's subpoena issued to them . . . .[58]

The Chairman provided one last offer to StemExpress and [redacted] to comply with the subpoenas.[59] After receiving no substantive reply from StemExpress' new counsel, the Panel, on September 21, 2016, voted to recommend that the House of Representatives hold StemExpress and [redacted] in contempt of Congress.[60]

Based on the facts outlined above and the supporting documentation, I request that the Department of Justice conduct a thorough investigation into whether StemExpress committed any violation of federal law during its evasive interactions with Congress. If you have any questions about this request, please contact T. March Bell, Chief Counsel and Staff Director, at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chair
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member

[57] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to Frank Radoslovich, counsel for StemExpress (Sept. 8, 2016).
[58] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to Frank Radoslovich, counsel for StemExpress (Sept. 8, 2016) at 4.
[59] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to Frank Radoslovich, counsel for StemExpress (Sept. 8, 2016) at 4.
[60] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Business Meeting, unedited transcript, Sep. 21, 2016.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 Rayburn House Office Building
Washington, DC 20515–6115

Majority (202) 225-2927
Minority (202) 225-3641

December 21, 2016

VIA EMAIL

The Honorable Loretta Lynch
Attorney General
c/o Office of Legislative Affairs
U.S. Department of Justice
950 Pennsylvania Ave NW
Washington, DC 20530

Dear Attorney General Lynch:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion providers and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, the Panel investigators have uncovered documents and received testimony from confidential informants indicating that several entities may have violated federal law, specifically Title 42 U.S.C. § 289g-2, which forbids the transfer of fetal tissue for valuable consideration. These entities are as follows:

Planned Parenthood Mar Monte
Planned Parenthood Shasta Pacific (Northern California)
Planned Parenthood Los Angeles
Planned Parenthood Pacific Southwest
Novogenix

For your review and careful study, I have attached herewith [redacted] that present facts and supporting documentation of possible criminal misconduct by the entities listed above. I urge your office to conduct a thorough investigation into possible violations of federal law and, if you agree that such violations occurred, to take all

appropriate action. If you have any questions about this request, please contact T. March Bell at (202) 226-9027, March.Bell@mail.house.gov.

Sincerely yours,

Marsha Blackburn
Chairman
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky
Ranking Member
Select Investigative Panel

V. Case Studies of the Fetal Tissue Industry – The Middleman Model

Chapter V Redaction Key:

StemExpress, LLC

1. [PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA), and is charge of the PPFA Manual of Medical Standards and Guidelines.

2. [PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

3. [the Founder and CEO] is the founder and CEO of StemExpress, LLC (StemExpress)

4. [ABR's Procurement Manager] is the procurement manager at Advanced Bioscience Resources, Inc.

5. [FDA Consumer Safety Officer # 1] is a consumer safety officer at the U.S. Food and Drug Administration.

6. [FDA Consumer Safety Officer # 2] is a consumer safety officer at the U.S. Food and Drug Administration.

Novogenix Laboratories, LLC

1. [PP Witness # 1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA), and is charge of the PPFA Manual of Medical Standards and Guidelines.

2. [PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.

3. [Founder and Executive Director] is the founder and executive director of Novogenix Laboratories, LLC (Novogenix).

4. [Supervisor Consumer Safety Officer] is a supervisor consumer safety officer at the U.S. Food and Drug Administration.

5. [Consumer Safety Officer] is a consumer safety officer at the U.S. Food and Drug Administration.

DaVinci Biosciences, LLC/DaVinci Biologics, LLC

1. [DVB Executives] are the owners and managers of DaVinci Biosciences, LLC (DaVinci) and DaVinci Biologics, LLC (DVB).

2. [DVB Executive # 1] is the president of DaVinci and DVB.

3. [DVB Executives # 2 and 3] are founding members and officers of DaVinci and DVB.

Human Fetal Tissue Repository

1. [Einstein Executive Dean] is a senior official at the Albert Einstein College of Medicine.

2. [Einstein Vice-President, Government and Community Relations] is an official who handles government relations at the Albert Einstein College of Medicine.

3. [Einstein Vice-President, External Affairs] is an official who handles external relations at the Albert Einstein College of Medicine.

A. StemExpress, LLC: A Case Study

1. Summary

The Panel conducted an investigation of StemExpress, LLC (StemExpress) that uncovered evidence that StemExpress may have violated 18 § 1519, 42 § 289g-2, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), provisions of the California Health and Safety Law, the California Tax Revenue and Tax Code, and regulations promulgated by the U.S. Department of Health and Human Services (HHS).

a) Background of StemExpress

StemExpress was founded as a for-profit corporation with the California Secretary of State on March 4, 2010, by [the Founder and CEO].[131] On December 2, 2015, [the Founder & CEO] filed papers with the California Secretary of State that created the StemExpress Foundation, which is located at the same address as StemExpress.[132] It is unclear whether the Foundation is for-profit or non-profit, because its tax forms are not yet publicly available.

Before [the Founder and CEO] began StemExpress, she worked for Advanced Bioscience Resources, Inc. (ABR) another tissue procurement company that is established as a non-profit.[133]

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[131] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov.
[132] *Id.*
[133] For more details on ABR, see subsection B below.

ABR executives express a low opinion of the Founder & CEO. On an unedited Center for Medical Progress (CMP) videotape viewed by Panel Staff, [ABR's procurement manager] stated that [the Founder and CEO] ". . . is totally unethical, she worked for us, she went into our office one night, looked around, and took everything we had, and started her own business, and quit the next day. I will tell you that."[134]

The U.S. Food and Drug Administration (FDA) had planned in 2014 to conduct an inspection of StemExpress based on the FDA's "priorities list."[135] The FDA only has jurisdiction over fetal tissue that is intended for transplantation into human subjects. The inspection was dropped after an FDA consumer safety officer determined that StemExpress:

> . . . essentially collected blood and tissue products including stem cells, whole blood, leukocytes, etc . . . from a human donor. . . . The company advertises for, collects from (on-site), and maintains, [a] potential donor database . . . . Their products are **not** intended for transplant, implant or transfer into a human recipient.[136]

The FDA consumer safety officer stated: "I plan to tell StemExpress that they do not have to register as a human tissue establishment [and thus are not under FDA jurisdiction] because they do not sell [a] product that is intended for transfer into a human recipient."[137]

b) History of the Panel's Interactions with StemExpress

On December 17, 2015, the Panel sent StemExpress a document request letter that requested a list of all entities from which it procured fetal tissue, a list of all entities to which it sold or donated fetal tissue, an organization chart, all communications that direct its employees to procure fetal tissue, a list of all federal funds the firm received, accounting records, and all StemExpress banking records related to the procurement, sale, donation, distribution or shipment of fetal tissue.[138]

StemExpress only produced the names of abortion clinics to the Panel from which it had procured fetal tissue that also had been previously produced to investigations into the fetal tissue industry conducted by the Senate Committee on the Judiciary and the House Committee on Energy and Commerce.[139] StemExpress refused to produce voluntarily the names of all of the clinics from which it procured fetal tissue.[140] Due to this lack of cooperation, on February 12, 2016, the Panel issued a subpoena to StemExpress. The subpoena demanded copies of the

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[134] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNND0569_20140406173620.
[135] Email from [Consumer Safety Officer # 1], U.S. Food and Drug Administration, to [Consumer Safety Officer # 2], U.S. Food and Drug Administration (Aug. 15, 2014).
[136] *Id.* (emphasis in original).
[137] *Id.*
[138] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [Founder and CEO, StemExpress, LLC] (Dec. 17, 2015), Exhibit 5.1.1
[139] StemExpress Second Response to Senate Judiciary Committee. [STEM.JUD00000024; STEM.HOUSE SELECT 0057] Exhibit 5.1.
[140] StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016) Exhibit 5.2.

documents first requested in the December 17, 2015 letter, including the communications with its employees, accounting documents, and all banking records.[141]

StemExpress produced communications to the Panel that spanned only two years instead of the five required by the subpoena, and these were so replete with redactions as to render them unusable.[142] StemExpress produced only "roll-up" accounting summaries, not the required primary source accounting records.[143] To date, the Panel has not received a single accounting record from StemExpress.

The Panel, in a February 12, 2016, subpoena to StemExpress (which is discussed below), requested all communications and documents that identify any federal, state, or local government funds that StemExpress received either directly or indirectly.[144] StemExpress responded that it had nothing responsive to produce. ("StemExpress has confirmed that there are no communications or documents responsive to this . . . .")[145] Despite that representation, the Panel discovered that StemExpress received more than $9,000 in a small business loan from the U.S. Small Business Administration.[146]

StemExpress refused to produce any of its banking records as required by the subpoena. However, in a production from another entity, the Panel discovered the name of StemExpress' bank and its account number and issued a subpoena to that bank.[147] Due to StemExpress' refusal to comply with repeated subpoenas, on September 21, 2016, the Panel unanimously recommended that the House of Representatives hold StemExpress in contempt of Congress (for more details on this, see subsection 7: The Select Panel Recommends that the House Find StemExpress in Contempt of Congress).[148]

As Rep. Duffy (WI-7) noted during the meeting at which the contempt recommendation was voted:

> This committee nine months ago sent out a request for documents to StemExpress. And they failed to comply completely with that subpoena. Now, we have sent other subpoenas to tissue procurement businesses and they have complied. They had no problem sharing their information with this committee. But StemExpress, however, failed to fully comply. And we are not talking about really sensitive information. We are talking about their banking records, their accounting records. That is what we have asked for. What is in the

[141] Subpoena to StemExpress, LLP, (Feb. 12, 2016), Exhibit 5.3.
[142] StemExpress, Third Response to House Select Investigative Panel Subpoena (Apr. 11, 2016) [STEM.HOUSE.SELECT0064 – STEM.HOUSE.SELECT_0670], Exhibit 5.4.
[143] *See* Letter from Amandeep S. Sidhu, McDermott Will & Emery, to T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel 1 (Mar. 18, 2016) (emphasis in original); *See* Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Blackburn, Chairman, House Select Investigative Panel 2 (May 6, 2016).
[144] Subpoena to StemExpress, Exhibit 5.3.
[145] *Id.*, Exhibit 5.3
[146] *See* Center for Effective Government website, www.FedSpending.org.
[147] *See* Subpoena to Five Star Bancorp (Apr. 29, 2016).
[148] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Business Meeting, unedited transcript (Sept. 21, 2016).

> banking and accounting records that is so secretive that they won't comply with a congressional lawful subpoena? That is the question that we have to ask ourselves. What don't they want us to know?[149]

The Panel had reason to ask the questions posed by Rep. Duffy. An examination by Panel staff of StemExpress' bank records found payments to Shred-It USA that, for the most part, corresponded with dates of document demand letters from congressional investigations of the fetal tissue industry, subpoenas from the Panel, and StemExpress productions to the Panel and other congressional inquiries. StemExpress bank records dating back to November 2012 revealed there were no payments made to Shred-It USA prior to the first congressional investigations into the fetal tissue industry.[150] The chart below shows those payments:

Congressional Action	**Payment to Shred-It-USA**	**StemExpress Action**
July 16, 2015 – Senate Judiciary Committee document request	August 13, 2015	August 19, 2015 – StemExpress production to Senate Judiciary Committee
August 7, 2015 – Energy & Commerce Committee document request	August 13, 2015	August 21, 2015 – StemExpress production to Energy & Commerce Committee
August 25, 2015 – Energy & Commerce Committee document request	August 25, 2015	September 11, 2015 – StemExpress production to Energy & Commerce Committee in response to questions from briefing
September 9, 2015 – Oversight & Government Reform Committee document request	September 29, 2015	October 9, 2015 – StemExpress production to Oversight & Government Reform Committee
September 17, 2015 – Senate Judiciary		September 24, 2015 – StemExpress production to Senate Judiciary Committee

[149] *Id.* at 27.

[150] Panel staff analysis of StemExpress, LLC, payments to Shred-It-USA drawn from documents produced by Five Star Bancorp to the Panel.

Committee document request letter		
December 17, 2015 – Select Investigative Panel document request	January 12, 2016	January 15, 206 – StemExpress production to Select Investigative Panel
	January 27, 2016	February 1, 2016 – StemExpress production to Select Investigative Panel
February 12, 2016 – Select Investigative Panel subpoena	March 12, 2016	March 28, 2016 – StemExpress production to the Select Investigative Panel
	April 26, 2016	May 10, 2016 – StemExpress production to Select Investigative Panel

2. StemExpress Business Model

StemExpress' business model was to obtain fresh fetal tissue from a large number of abortion clinics and provide on-demand fetal tissue to researchers around the world. In order to do that, the firm needed a ready supply of fetal tissue. The only way to achieve that was to dramatically increase the number of abortion clinics from which it obtained fetal tissue. In order to provide fetal tissue to the largest number of customers, StemExpress had to increase the number of abortion clinics from which it procured fetal tissue. A profile of [the Founder and CEO] published in July 2015, noted: "[StemExpress was] opening a branch in Washington, D.C., in the next three months and is looking at the possibility of a site in Europe as well."[151]

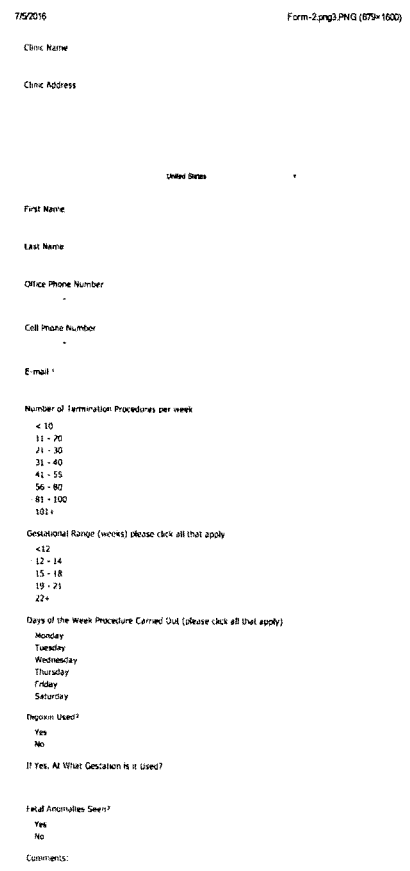
The Panel notes that StemExpress' entry into the tissue procurement business coincided with an increase in federal government grants for research using fetal tissue. The average amount of time for a researcher to obtain a grant for fetal tissue research from the National Institutes of Health (NIH) is three years. The Panel reviewed all grants that involved fetal tissue (see Chapter IX). That review found the number of grants using fetal tissue declined from fiscal years 2009 through 2012, but, starting in fiscal year 2013, there was an upsurge.

a) Marketing Activities

StemExpress recruited and screened abortion clinics from which it could procure saleable tissue for researchers.[152] The company sought information about the number of abortions the

[151] "2015 Women Who Mean Business: [Founder and CEO and StemExpress] founder and CEO, Stem Express [sic]," Sacramento Business Journal," June 19, 2015.
[152] StemExpress Website Recruitment Form for Abortion Clinics. See following page.

clinics performed each week, the gestational ages of fetuses scheduled to be aborted, the days the abortions were done, whether digoxin[153] was used (which would taint the tissue and thus render the tissue useless for research), and, if so, at what gestation digoxin was used. A copy of the Website Recruitment Form for abortion clinics follows:



7/5/2016 Form-2.png3.PNG (679×1600)

Clinic Name

Clinic Address

United States

First Name

Last Name

Office Phone Number

Cell Phone Number

E-mail *

Number of Termination Procedures per week

- < 10
- 11 - 20
- 21 - 30
- 31 - 40
- 41 - 55
- 56 - 80
- 81 - 100
- 101 +

Gestational Range (weeks) please click all that apply

- <12
- 12 - 14
- 15 - 18
- 19 - 21
- 22+

Days of the Week Procedure Carried Out (please click all that apply)

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday
- Saturday

Digoxin Used?

- Yes
- No

If Yes, At What Gestation is it Used?

Fetal Anomalies Seen?

- Yes
- No

Comments:

[153] Digoxin is a heart medication that sometimes is injected into the amniotic fluid or fetus to cause fetal demise before surgical or induction abortion. *See* Abortion in California: A Medical-Legal Resource, http://californiaabortionlaw.com/wp/?page_id=135.

The firm developed an aggressive marketing strategy directed toward abortion clinics. StemExpress had booths at both the 2014 and 2015 annual meetings of the National Abortion Federation (NAF). StemExpress was a silver-level sponsor at the NAF meeting: StemExpress paid NAF $5,000 for that status in 2014 and $10,000 in 2015.[154] StemExpress had a half-page advertisement in the program for both the 2014 and 2015 NAF meetings.[155] At the conferences, StemExpress distributed a brochure to NAF members that promised abortion clinics they would be "[f]inancially profitable" if they allowed StemExpress to procure tissue from the clinics. The brochure stated: "By partnering with StemExpress" the clinics will not only help research "but [they] will also be contributing to the fiscal growth of [their] own clinic[s]."[156] The full brochure and the two half-page ads follow.

[154] Email from name redacted, Vice President, Corporate Development, StemExpress, LLC, to name redacted, Subject: Partnership Agreement – StemExpress (Mar. 25, 2015) [NAF-000045]; Partnership Agreement between StemExpress, LLC, and the National Abortion Federation (Mar. 25, 2015) [NAF-000046 – NAF-000053], Exhibit 5.5.

[155] NAF 2014 and 2015 advertisements. *See* Exhibit 5.1.9.

[156] StemExpress, LLC, brochure distributed at National Abortion Federation Meeting, undated [NAF-000001 – NAF-000004]. NAF produced to the Panel a black-and-white version of the brochure. A color copy that is identical, with the exception of a StemExpress employee's business card, that the Panel found on the Internet is reprinted in the Report.

stem express

About StemExpress

StemExpress is a California-based biomedical company that provides qualified research laboratories with human cells, fluids, blood and tissue products for the pursuit of disease detection and cure. We procure, preserve, isolate and deliver cell lines exclusively to research facilities across the world. StemExpress products are not available for patient care. Stem Express is accredited by an independent biomedical Institutional Review Board.

"Our partnership with StemExpress is beneficial in a number of ways. First, it allows us to contribute to life-saving research that is advancing diagnostic and medical care. Second, StemExpress has a Plug-in Solution that allows us to add additional clinics quickly. Lastly, I feel confident that our patient's anonymity is secure through their strict protocols and practices."
[redacted] Planned Parenthood Mar Monte

Advancing BioMedical Research Together

Join the StemExpress partner program that fiscally rewards clinics for contributing to the advancement of life-saving research — with a solution that is easy to incorporate into your clinic practices. StemExpress is a California-based biomedical company that provides human tissue products ranging from fetal to adult tissues and healthy to diseased samples to many of the leading research institutions in the world. Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines.

Partnering with Obstetrical-Care Clinics

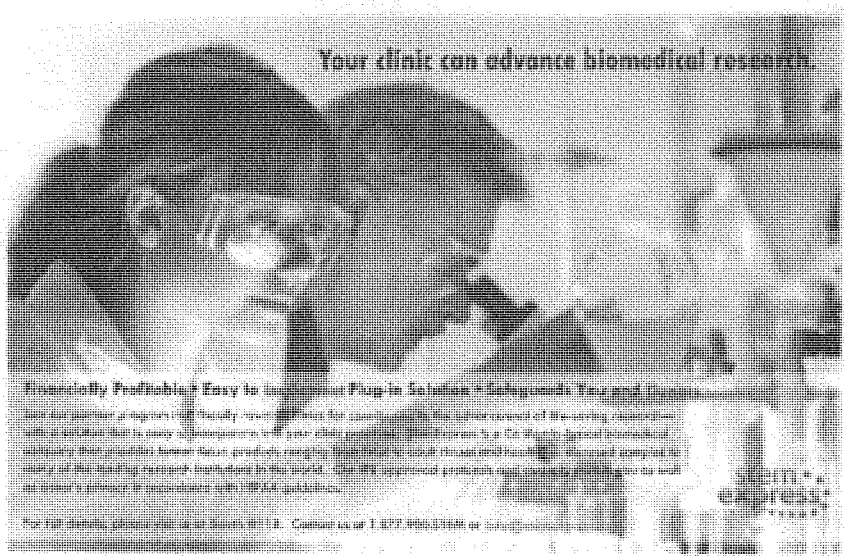
Cell-free fetal DNA circulates in maternal blood throughout pregnancy. Noninvasive, stem cell free methods to obtain fetal DNA are being used for earlier detection of genetic diseases as well as reproductive decision-making. Research pioneers who develop noninvasive diagnostic technologies rely on the blood samples that are collected from hospitals and clinics throughout the United States.

Easy to Implement Program + Financial Profits

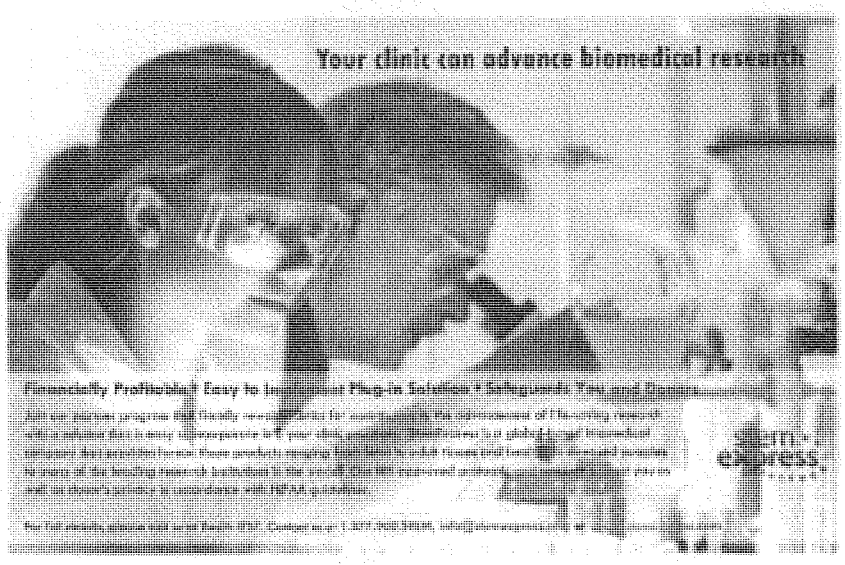
StemExpress promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with StemExpress, not only are you offering a way for your clients to participate in the unique opportunity to facilitate life-saving research, but you will also be contributing to the fiscal growth of your own clinic. The stem cell rich blood and raw materials that are usually discarded during obstetrical procedures can, instead, be expedited through StemExpress to research laboratories with complete professionalism and source anonymity.


stem
express

NAF 2014 Conference



NAF 2015 Conference



b) StemExpress Seeks a Nationwide Network of Abortion Clinics

During the timeframe of StemExpress' conference marketing scheme, it sought a contractual relationship with NAF, a national association of independent abortion clinics. Documents produced by NAF to the Panel reveal that, for at least a year, StemExpress and NAF actively negotiated a "Group Purchasing" contract. This effort revealed StemExpress' strategy to increase the number of abortion clinics from which it obtained fetal tissue, thereby enabling StemExpress to both promise customers a quick response *and* achieve higher revenues.

The Panel sought to understand the proposed NAF-StemExpress relationship. The proposed partnership agreement raises questions of whether StemExpress and NAF both saw the proposed contract as a means to increase their respective revenue streams.

An email NAF produced to the Panel shows that the negotiations with StemExpress date back to at least February 2014. On February 20, 2014, NAF's Group Purchasing Manager sent an email that stated:

> I spoke with [name redacted] from Stem Express [sic] today regarding them becoming a Group Purchasing vendor in the program. As [name redacted] and I discussed yesterday theirs is a unique service that would not fall under the 3% administrative fee realm. From my conversation today I feel it is even more unique than I initially anticipated.
>
> Here is a summarization of the process as [named redacted] described it:
>
> 1. Stem Express collects the maternal blood from the patient and/or the fetal tissue after the procedure.
> 2. Either a Stem Express employee located at the clinic or a clinic employee gathers and stores the collection.
> 3. The collection (product) is sent to the lab and cells are isolated for research.
> 4. The participating clinic is paid by Stem Express a fee per collection.
>
> The fact that Stem Express is the payer and our member is the payee changes the fee structure. Perhaps we can access a fee or value for each member that participates or base it on financial payouts to the member. For instance, when a member is paid up to $500, Stem Cell [sic] would owe X amount to NAF or a flat yearly fee based on the number of participating members.

> I know the final decision would be [name redacted]'s regarding payment terms however I wanted to have a concrete suggestion to put forth. What are your thoughts?[157]

An unidentified person at NAF responded on February 20, 2014: "I like the idea of setting benchmarks and NAF getting fees based on usage."[158] StemExpress and NAF actively and repeatedly discussed the proposed draft contract in email exchanges.

In August 2014, StemExpress' accounting manager told a person within the company whose name was redacted: "This [proposed contract with NAF] looks like it aligns better with us."[159] On October 24, 2014, an unknown person at NAF emailed StemExpress: "Just checking in to see how the vendor agreement is coming."[160] In January 2015, [the Founder and CEO] sent an email to an unidentified person at NAF in which she explained that the StemExpress official charged with negotiating the NAF agreement "is no longer with the company and I wanted to make sure the vendor agreement doesn't get put on back burner so could you please resend this agreement and we will get it turned around to you."[161] An unidentified person at NAF responded:

> Well that explains her lack of response. I am glad you are still interested.
>
> I have attached an initial draft of an agreement. As I explained to [name redacted] this is unique as it is not a product therefore the standard admin[istrative] fee process does not apply.
>
> Please review the attached and fill in the blanks. Let me know if we need to [set up] a call to discuss.
>
> On another note, we are gearing up for our Annual Meeting in Baltimore. I will have a prospectus in the next week or so.[162]

On January 15, 2015, [the Founder and CEO] sent an email to NAF in which she stated:

> Attached is the draft agreement with marked up comments. It might be best to set up a conference call next week to discuss this in further detail as a lot of this agreement had language in it that looked like it was for a professional liability insurance company, which we clearly

[157] Email from Group Purchasing Manager, National Abortion Federation, to [redacted], Subject: RE: Stem Express [sic] GP Vendor (Feb. 20, 2014) [NAF-000016] (spacing in original), Exhibit 5.6.
[158] Email from [redacted] to [redacted], Subject: RE: Stem Express [sic] GP Vendor (Feb. 20, 2014) [NAF-000016], Exhibit 5.6.
[159] Email from [redacted], Accounting Department Manager, StemExpress, LLC, to [redacted], StemExpress, LLC, Subject: RE: NAF GP membership (Aug. 8, 2014) [NAF-000034], Exhibit 5.7.
[160] Email from [redacted], National Abortion Federation, to [redacted], StemExpress, LLC, Subject: RE: NAF GP membership (Oct. 24, 2014) [NAF-000034], Exhibit 5.7.
[161] Email from [redacted], CEO and Founder, StemExpress, LLC, to [redacted], Subject: RE: NAF GP membership (Jan. 6, 2015) [NAF-000033], Exhibit 5.8.
[162] Email from [redacted], National Abortion Federation, to [redacted] (Jan. 8, 2015) [NAF-000033], Exhibit 5.8.

> aren't, so I just wanted to make sure that we were on the same page about what should be included in this agreement.[163]

On February 18, 2015, [the Founder and CEO] wrote NAF: "I haven't forgotten to send this I have just been buried . . . I have been in the process of updating a few contracts here at the beginning of the year. The clinic contract is one of them. We should have it to you in the next two weeks."[164] NAF replied on February 27, 2015, "I have attached a revised agreement. Please submit any changes and contact me with any questions."[165]

In March 2015, StemExpress' vice president for corporate development sent NAF the firm's revised version of the partnership agreement:

> Please find a draft Partnership Agreement for your consideration. I've taken the liberty of reformatting a bit of it to follow our more-routine contract structure (no real change to the substantive contract). I removed the language pertaining to alternative donations ($5K and $10K) since we elected to go with $10K and participate in the upcoming NAF meeting . . . There will appear to be a lot of redlining in the Appendix, but this is largely an artifact of changing the content to reflect StemExpress business . . .
>
> If the agreement with changes are acceptable to you, please 'accept changes,' sign and return to me at your earliest convenience. If you need to make changes, please reply with your redline as soon as possible and I'll get the document turned around promptly.[166]

Below are excerpts of the March 25, 2015, draft partnership agreement between StemExpress and NAF:

> Services and Donation:
>
> (a) NAF commits to performing the services outlined in this document under Appendix A.
> (b) StemExpress agrees to make a donation to the NAF in the amount of US $10,000 and undertake the activities listed in Appendix B . . .

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[163] Email from [redacted], CEO and Founder, StemExpress, LLC, to [redacted], Subject: RE: NAF GP membership (Jan. 15, 2015) [NAF-000023]; Purchase Agreement between NAF and StemExpress, LLC (Jan. 10, 2015) [NAF-000024 – NAF-000032], Exhibit 5.9.

[164] Email from [redacted], CEO and Founder, StemExpress, LLC, to [redacted], Subject: FWD: NAF GP membership (Feb. 18, 2015) [NAF-000036], Exhibit 5.10.

[165] Email from [redacted], to [redacted], StemExpress, LLC, Subject: RE: NAF revised agreement (Feb. 27, 2015). [NAF-000036]; Partnership Agreement between the National Abortion Federation and Stem Express [sic], undated [NAF-000037 –NAF-000044], Exhibit 5.10.

[166] Email from [redacted], Vice President, Corporate Development, StemExpress, LLC, to [redacted], Subject: Partnership Agreement – StemExpress (Mar. 25, 2015). [NAF-000045]; Partnership Agreement between StemExpress, LLC, and the National Abortion Federation (Mar. 25, 2015) [NAF-000046 – NAF-000053], Exhibit 5.11.

Appendix A

NAF's Commitment

For the aforementioned sum mentioned in the section marked "Payment for Services," NAF commits to performing the following for one year to assist StemExpress in presenting its collection program to NAF members:

- Create and disseminate to NAF members correspondence from NAF's Group Purchasing Manager about StemExpress and the collection program twice yearly at the request of StemExpress.
- . . . Provide a cover letter for NAF's President and CEO pertaining to the StemExpress collection program which StemExpress can use to accompany marketing materials for NAF members.
- . . . Provide mailing list for StemExpress to send out marketing materials to NAF members regarding the background of StemExpress, its collection program, and benefits of member participation in the program.
- Provide assistance to StemExpress in gathering testimonials from existing program participants from among NAF members.
- . . . Supply StemExpress with a quarterly updated list of members.

Appendix B

StemExpress' Commitment

StemExpress commits to performing the following for one year to market its collection services to NAF members:

- . . . Create and produce marketing "slicks" on the background of StemExpress, its capabilities, and highlight participation benefits.
- Provide, at no charge to NAF, informative sessions or meetings that present the collection program.
- Develop client success stories on how StemExpress brought a value added service to participating members. This will help to inform members about StemExpress' offerings.
- Commit to attending NAF's Annual Meeting in April of each year.
- Pursue all leads from NAF, introducing StemExpress and what StemExpress' capabilities are.[167]

[167] *See* StemExpress, Third Response to House Select Investigative Panel Subpoena (Apr. 11, 2016) [STEM.HOUSE.SELECT0064 – STEM.HOUSE.SELECT_0670], Exhibit 5.4.

In April 2015, NAF replied:

> My apologies as my promise to respond by COB today comes with a delay. There is cause for concern regarding the added text under the Assignment section. It denotes, "StemExpress may assign this Agreement to an acquirer without notice . . . pursuant to an acquisition or merger of StemExpress involving greater than 50% of the company, provided further, that any respective successor or permitted assign shall thereby assume all of such StemExpress' rights, and shall be subject to all of such StemExpress' duties and obligations, hereunder.
>
> That clause takes away a discretion that is essential to the prescreen process and creates [a] privacy concern that we go to great lengths to protect. Although I agree there is no other changes that impact the substantive content, [name redacted], our general counsel, is giving it a quick read. I did think however that in the interest of time, you could respond to the deletion request noted above.[168]

NAF produced no further communications about its proposed partnership agreement with StemExpress. However, NAF's counsel told Panel staff that, during the timeframe when the Center for Medical Progress videos were made public, the organization's leadership had significant concerns about being involved with a tissue procurement business.

The Panel determined that StemExpress' brochure aimed at abortion clinics nationwide, and its attempted partnership agreement with NAF belies StemExpress' contention that it was losing money. Rather, those facts show StemExpress had a business model based on expansion of its market share.

c) StemExpress Seeks Partnership Agreement with Planned Parenthood Federation of America

Just as StemExpress sought a relationship with NAF, it also sought a contract with Planned Parenthood Federation of America (PPFA) and its affiliates. If the proposed relationships with PPFA and NAF had been successful, StemExpress would have had access to virtually every abortion clinic in the nation. [PP Witness #1] stated:

> So, we tried to do this, and at the national office we have a Litigation and Law Department that just really doesn't want us to be the middle people for this issue, right now. Because we were actually approached by StemExpress to do the same thing. One of the California affiliates said, "We're working with these people, we love it, we think every affiliate should work with them." And so we had a conversation, and we said, you know, what if we go out and

[168] Email from [redacted], National Abortion Federation, to [redacted], StemExpress, LLC, (Apr. 9, 2015) [NAF-00063], Exhibit 5.11.

> find everyone who is doing this and present everybody with a menu, and at the end of the day they just decided that right now, it's just too touchy an issue for us to be an official middleman.[169]

In a conversation with a CMP journalist, [PPFA Witness #3] confirmed that one of the major reasons that held PPFA back from a partnership agreement with a tissue procurement organization was because "we have [the] potential for a huge PR issue on doing this."[170] Despite PPFA's hesitancy due to public relations, StemExpress already had contracts with a number of PPFA affiliates.

d) StemExpress' Contracts with Abortion Clinics

StemExpress had contracts to procure fetal tissue from the following PPFA affiliates:

- Planned Parenthood Mar Monte (PPMM)
- Planned Parenthood Shasta Pacific (PPSP); and
- Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties (PPSB).[171]

StemExpress also had contracts with the following five independent abortion clinics:

- Camelback Family Planning (CFP)
- Cedar River Clinics (CRC)
- Presidential Women's Center (PWC)
- Women's Health Specialists (WHS)
- Family Specialists Medical Group (FPS)
- Little Rock Family Planning Services (LRFPS).[172]

Documents show that StemExpress never procured fetal tissue from Planned Parenthood San Bernardino, Women's Health Specialists, or Little Rock Family Planning Services.[173]

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[169] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] 28-29 (July 25, 2014).

[170] Center for Medical Progress video FNND0569_ 20150226165708 (Feb. 26, 2015) produced to the Committee on Oversight and Government Reform.

[171] Exhibit 5.4; Services Agreement between StemExpress, LLC, and Planned Parenthood Mar Monte (Apr. 1, 2010) [STEM.HOUSE.SELECT_0167 – STEM.HOUSE.SELECT_0189], Services Agreement between StemExpress, LLC, and Planned Parenthood Shasta Pacific (May 5, 2012) [STEM.HOUSE.SELECT_0170 – STEM.HOUSE.SELECT_0172], Services Agreement between StemExpress, LLC, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties (Oct. 23, 2013) [STEM.HOUSE.SELECT_0181 – STEM.HOUSE.SELECT_0183], Exhibit 5.12.

[172] StemExpress, LLC, produced to the Panel invoices covering numerous years from Planned Parenthood Mar Monte, and Planned Parenthood Shasta Pacific. Camelback Family Planning, Cedar River Clinics, Presidential Women's Center, and Family Specialists Medical Group produced to the Panel invoices to StemExpress, LLC. *See* Letter from Mark Merin, counsel to Women's Health Specialists, to Panel staff 2-3 (Apr. 11, 2016); Letter from Bettina E. Brownstein, counsel for Little Rock Family Planning Services 1 (Oct. 10, 2016).

[173] Services Agreement between StemExpress, LLC, and Camelback Family Planning, undated [CFP000002 – CFP000006], Services Agreement between StemExpress, LLC, and Cedar River Clinics (Nov. 15, 2013) [CRC001 – CRC 006], Services Agreement between StemExpress, LLC, and Presidential Women's Center (Feb. 14, 2014) [PWC-0001 – PWC0003], Exhibit 5.13; Letter from Mark Merin, counsel to Women's Health Specialists, to Panel staff (Apr. 11, 2016); Letter from Bettina E. Brownstein, counsel for Little Rock Family Planning Services 1 (Oct. 10, 2016)

Under the terms of its contracts:

- StemExpress paid Planned Parenthood Mar Monte $55 for each fetal tissue specimen and $10 for each maternal blood sample.[174]

- StemExpress paid Planned Parenthood Shasta Pacific $55 for each fetal tissue specimen and $10 for each maternal blood sample.[175]

- StemExpress had a two-tier payment plan with Planned Parenthood San Bernardino: $75 for fetal tissue samples and $50 for maternal blood, if it was "collected solely" by Planned Parenthood San Bernardino staff; if StemExpress staff collected the samples, "then there would be a cost adjustment . . ."[176]

- StemExpress paid Camelback Family Planning $200 for 5cc or more of liver tissue and three tubes of maternal blood; $250 for 5cc of liver and thymus of the same fetus and three tubes of maternal blood; and $75 for other fetal tissue "as requested by StemExpress" with three tubes of maternal blood.[177]

- StemExpress paid Cedar River Clinics $50 for maternal blood; $75 for each fetal tissue specimen; $125 for fetal tissue with an IDS blood sample; $125 for maternal blood and tissue kits; between $100 - $400 for fetal blood samples; $50 for blood; $75 for each fetal tissue specimen; and face value ($25) for gift cards distributed to "blood donors," if Cedar River Clinics staff collected the blood and tissue.[178]

- StemExpress paid Presidential Women's Center $50 per 60cc of maternal blood, and $75 for each fetal tissue specimen, if collected solely by clinic staff:[179] "If StemExpress staff is onsite to physically collect the sample, then there would be a cost adjustment for the collection of the sample."[180] StemExpress paid Family Specialists Medical Group $55 for each tissue sample, and $10 for maternal blood.[181]

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[174] Exhibit 5.12. H. Res. 461 did not mention maternal blood; thus, the Panel did not examine StemExpress' role in the procurement or sales of maternal blood. StemExpress' practices when it came to the procurement and sale of maternal blood are indicative of its profit-driven business model, and will be discussed in the Revenue Growth section below.
[175] *Id.*
[176] *Id.*
[177] Services Agreement between StemExpress, LLC, and Camelback Family Planning, undated [CFP000002 – CFP000006], Exhibit 5.13.
[178] Services Agreement between StemExpress, LLC, and Cedar River Clinics (Nov. 15, 2013) [CRC001 –CRC 006], Exhibit 5.13.
[179] Services Agreement between StemExpress, LLC, and Presidential Women's Center (Feb. 14, 2014) [PWC-0001 – PWC0003], Exhibit 5.13.
[180] *Id.*
[181] *Id.*

- StemExpress paid Women's Health Specialists $50 per 60 ccs of maternal blood and $75 "for the collection of fetal tissue, including each tissue organ/component (e.g., 1 heart, 1 liver, 1 brain = 3 component[]s X $75 each = $225) . . ."[182]

e) Impact of StemExpress Contracts on Clinical Practices

The Panel sought to determine whether the clinics changed their clinical practices in order to increase the amount of tissue samples StemExpress could obtain and thereby generate more revenue to the clinics. Through its review of the unedited CMP videotapes, the Panel learned that Cedar River Clinics (CRC), by its own admission, changed its clinical practices. [Clinic Executive #1] had the following exchange with a CMP journalist:

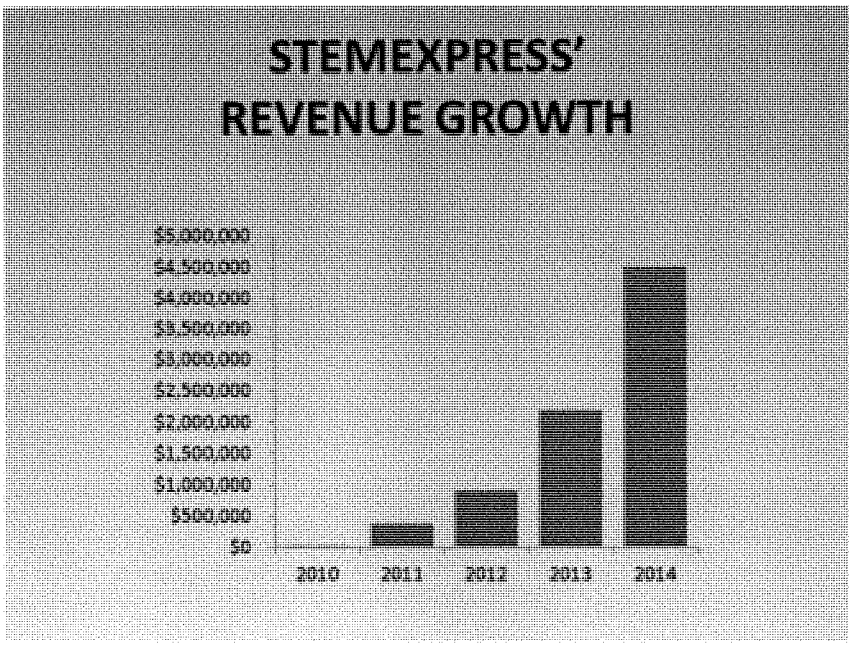
> CMP Journalist: [C]ould we just get a certain number of liver from you.
>
> [Clinic Executive #1]: Liver's a big thing right now. We just actually increased our gestation for dig[oxin], so that we could be able to get more liver, bigger liver.[183]

[PP Witness #1] testified that she changed abortion procedures to procure specific orders for fetal tissue (see Chapter VIII). [PP Witness #1] made similar statements on a Center for Medical Progress videotape.

3. StemExpress Revenue Grows from $156,312 to $4.5 Million

Between 2010 and 2014, StemExpress experienced tremendous revenue growth. In 2010, its revenue was $156,312. During 2011, that figure more than doubled to $380,000, and a year later, in 2012, StemExpress' revenue nearly tripled to $910,000. By 2013, its revenue was $2.20 million, and in 2014, the revenue had once again more than doubled to $4.50 million.

[182] Letter from Mark Merin, counsel to Women's Health Specialists, to Panel staff (Apr. 11, 2016), Exhibit 5.13.
[183] Center for Medical Progress videotape FNND0569_20140407161401 (Apr. 7, 2014) produced to the Committee on Oversight and Government Reform.



A profile of [the Founder and CEO] noted:

> She started StemExpress with just $9,000, running the business out of her Placerville home. She quickly found that there was indeed a demand for the company's products. Several new clients contacted her each week, without any active marketing, as word about StemExpress spread along the scientific grapevine.
>
> The company ranked No. 363 [in 2014] on the Inc. 500 list of fastest growing private companies, with 1,315 percent growth over three years and revenue of $2.2 million in 2013, and it ranked No. 35 on Inc.'s list of the fastest growing women-led companies in the country.[184]

The Panel sought to determine an accurate picture of StemExpress' revenues and costs associated with fetal tissue procurement. StemExpress presented conflicting accounts. For

[184] "2015 Women Who Mean Business: [Redacted], founder and CEO, StemExpress," Sacramento Business Journal, June 19, 2015.

example, [the Founder and CEO] stated to the Committee on Energy and Commerce: "StemExpress believes that it is losing money [on fetal tissue]."[185] StemExpress produced a list to the Panel of its estimated costs and expenses associated with fetal tissue procurement which purported to show that StemExpress lost money on fetal tissue.[186] StemExpress' counsel represented that the reports "were generated by StemExpress personnel directly from the company's accounting and software systems."[187] When she was asked to document StemExpress' costs to obtain fetal tissue, [the Founder and CEO] stated that "StemExpress doesn't have a spreadsheet or matrix for all of its costs," and acknowledged that the firm's estimated costs and expenses were produced by the firm's lawyers.[188] These conflicting statements redoubled the Panel's efforts to obtain accounting records.

a) StemExpress' Estimated Costs and Expenses Indicates That It May Have Made a Profit

A comparison of invoices, attorney-created accounting documents, and productions from multiple StemExpress customers shows that the firm may have made a profit when procuring and transferring fetal tissue. The Panel's cost analysis shows StemExpress overstated some of its labor costs, and claimed shipping, supplies, and infectious disease screenings as expenses. These costs were charged to researchers and thus cannot be costs that StemExpress can count against its revenue. StemExpress has consistently refused to produce subpoenaed accounting documents that the Panel requires to complete its analysis.

Attorneys for StemExpress created several cost estimates (orange numbers) that purport to show that StemExpress loses money each time it procures a fetal tissue sample and ships it to a customer. Shown in orange, the cost estimates produced by the attorneys are inconsistent with accounting records produced by StemExpress itself. For example, the Panel determined there was a discrepancy among the firm's cost items, StemExpress' contracts with the abortion clinics at which it procured fetal tissue, and invoices from abortion clinics to StemExpress. The firm contended that $55 for clinic reimbursement consisted of technician space, storage of supplies, blood draw chair usage, and consent space. Both the contracts with the abortion clinics and the invoices from the abortion clinics to StemExpress show the firm paid $55 per fetal tissue sample. In another example, the management labor costs at one hour per item ordered, which are counted twice, are dramatically inconsistent with the number of orders actually handled by StemExpress. Similarly, StemExpress estimates do not allocate any costs (such as mileage) to maternal blood which is harvested at the abortion clinic at the same time the human fetal tissue is harvested.

[185] StemExpress Briefing Notes, Committee on Energy and Commerce (Aug. 25, 2015), Exhibit 5.14.
[186] StemExpress, LLC, StemExpress Estimated Costs and Expenses Associated with Fetal Tissue Procurement (2011-2016) (May 10, 2016) [STEM.HOUSE.SELECT_0915], Exhibit 5.15.
[187] StemExpress, LLC, StemExpress Sixth Response to House Select Panel Subpoenas (May 10, 2016) [STEMHOUSE.SELECT_0908], Exhibit 5.16.
[188] StemExpress Briefing Notes, Exhibit 5.14.

COMPARISON OF STEMEXPRESS COST ANALYSIS WITH GENERALLY ACCEPTED INDUSTRY STANDARDS FOR ONE UNIT OF FETAL TISSUE IN 2013

COST ITEMS AND ESTIMATE PRODUCED BY STEMEXPRESS

ADJUSTED BASED ON REASONABLE INDUSTRY STANDARDS

COSTS ALLOCATED TO MATERNAL BLOOD ESTIMATED AT 50%

Cost Item	Description	Estimated Time	Estimated Cost/Expense	Recalculated Time	Recalculated Cost/ Expense	% Costs for Maternal Blood
Procurement Management Labor	Receive and evaluate purchase order, enter into Computer system and task board, assign to clinics.	1 hour x $35	$25.00	1 hour x $35	$35.00	$16.25
Packaging Supplies Labor	Packaging all supplies needed for procurement.	1 hour x $10	$10.00	1 hour x $10	$10.00	$3.50
Shipping	Supplies to Clinic	N/A	$15.00		$15.00	$7.50
Mileage	Mileage paid to technician (.56/mile)	N/A	$75.00		$75.00	**$35.00**
Supply cost	Box, conical tube, media, petri dish, labels, biohazard bag, gel packs, etc.	N/A	$30.00		$30.00	**$15.00**
Technician Base Labor	Patient consent, procurement, paperwork packaging.	8 hour x $10	$80.00	1 hour x $10	$10.00	**$5.00**
Technician Supplemental Compensation	Technician Supplemental Compensation	N/A	$30.00		$0.00	**$0.00**
Clinic Reimbursement	Technician space, storage of supplies, blood draw chair usage, consent space	N/A	$55.00		$55.00	**$27.50**
Infectious Disease Draw	Supplies: tubes, labels, needle, biohazard bag, etc.	N/A	$15.00		$15.00	**$7.50**
Infectious Disease Screening	Screening for HIV, HepB, HepC, LCMV	N/A	$70.00		$70.00	**$35.00**

Shipping	Average Shipment cost to the Lab (blood and/or tissue)	N/A	$20.00		$20.00	**$10.00**
Procurement Management Labor	Review paperwork, communications with courier, communications with researcher	1 hour x $35	$35.00		$35.00	**$5.00**
Product Receipt	Receipt of product at front desk, check into Sage, check into log	1 hour x $15	$15.00	.25 hour x $15	$4.00	**$2.00**
Inventory & Supply Management	Prorated stores management	1 hour x $20	$20.00	.25 hour x $20	$5.00	**$2.50**
			$495.00		**$351.50**	**175.75**

Sample review of a sale of maternal blood to customer Baylor per invoice #1940 of 1/12/2013

Sale price for Tissue $250.00

Disease screening charged to client $125.00

Shipping charged to client $85.00

Total Revenue obtained from this sale $460.00

Estimated cost of Tissue (per above) $175.75

Sample review of a sale of fetal tissue to customer Baylor per invoice #1940 of 1/12/2013

Sale price for Tissue $250.00

Disease screening charged to client $125.00

Shipping charged to client $85.00

Total Revenue obtained from this sale $460.00

Estimated cost of Tissue (per above) $351.00

b) StemExpress Used Deceptive Trade Practices to Obtain Maternal Blood at Zero Cost

The Panel's investigation revealed that, while StemExpress paid market prices for maternal blood in some settings, it obtained blood from abortion clinic patients without payment to the women.

While blood donations and sales are not covered by 42 U.S.C. § 289g-2, StemExpress' procurement and sales of maternal blood is indicative of how profit drove the company. StemExpress paid abortion clinics between $10 and $75 for maternal blood. StemExpress paid nothing to the blood donors at the clinics, with the sole exception of Cedar River Clinics, where it provided $25 gift cards to patients who donated blood. Outside of abortion clinics, however, StemExpress directly paid donors. The Panel obtained a photograph that demonstrates that StemExpress offered women the opportunity to "Donate your blood and Get $25."[189] The photograph of a company booth, has a sign on it which states: "Need Cash: $25 . . . per [blood] donation . . ."[190] For example, a brochure that sought blood donations produced by StemExpress to the Panel shows that the firm paid women outside of abortion clinics: "All of our donors receive a gift card for their donation ranging from $25-$250. . . . In 2014 StemExpress gave out over $140,000 in gift cards to donors . . ."[191]

StemExpress' website shows it sold (and continues to do so) maternal blood for between $340 and $510;[192] peripheral blood for between $115 and $2,464;[193] and umbilical cord blood for between $76 and $10,885.[194] StemExpress' collection of blood shows that the firm's focus is on profits, not on informing patients in abortion clinics who donate their blood that they have the opportunity to be paid for their blood elsewhere.

The Panel sought to determine the attitude of StemExpress' contractors, PPFA and its affiliates, toward StemExpress' practice of how it obtained blood. The PPFA executive responsible for the organization's medical guidelines and practices was asked repeatedly by the Panel whether she was troubled by StemExpress' remuneration for women's blood outside of abortion clinics, while it paid nothing for the blood of vulnerable women who were about to undergo an abortion. Despite repeated questions, the senior PPFA executive declined to answer.[195]

StemExpress made up to $10,875 in profit for sale of an individual blood product. While there is no law that bars a firm from valuable consideration for the sale of maternal or umbilical blood, the fact that StemExpress had such a large profit margin on its blood is key to understanding the firm.

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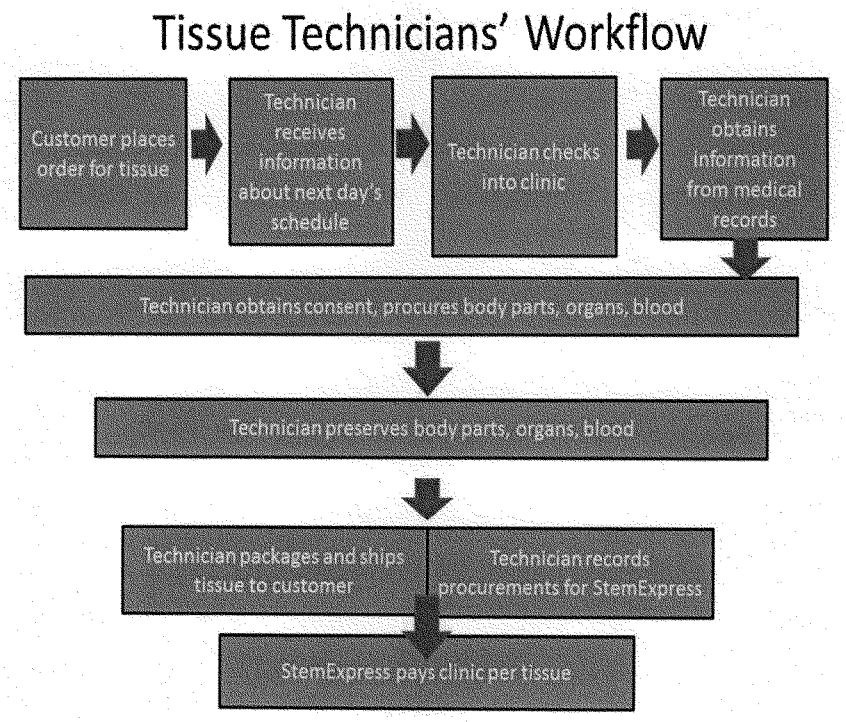
[189] Photograph of StemExpress, LLC, blood donation booth, Exhibit 5.17.
[190] Transcribed Interview of [PP Witness #1](Oct. 6, 2016) at 20.
[191] StemExpress, LLC, Donate Blood and Bone Marrow with StemExpress, undated 2 [STEM.HOUSE.SELEC_0192 – STEM.HOUSE.SELECT_0195], Exhibit 5.18.
[192] StemExpress website, Maternal Blood, http://stemexpress.com/product-category/maternal-blood/
[193] StemExpress website, Peripheral Blood, http://stemexpress.com/product-category/peripheral-blood/.
[194] StemExpress website, Umbilical Cord Blood, http://stemexpress.com/product-category/umbilical-cord-blood/.
[195] *See* Transcribed Interview of [PP Witness #1] (Nov. 1, 2016).

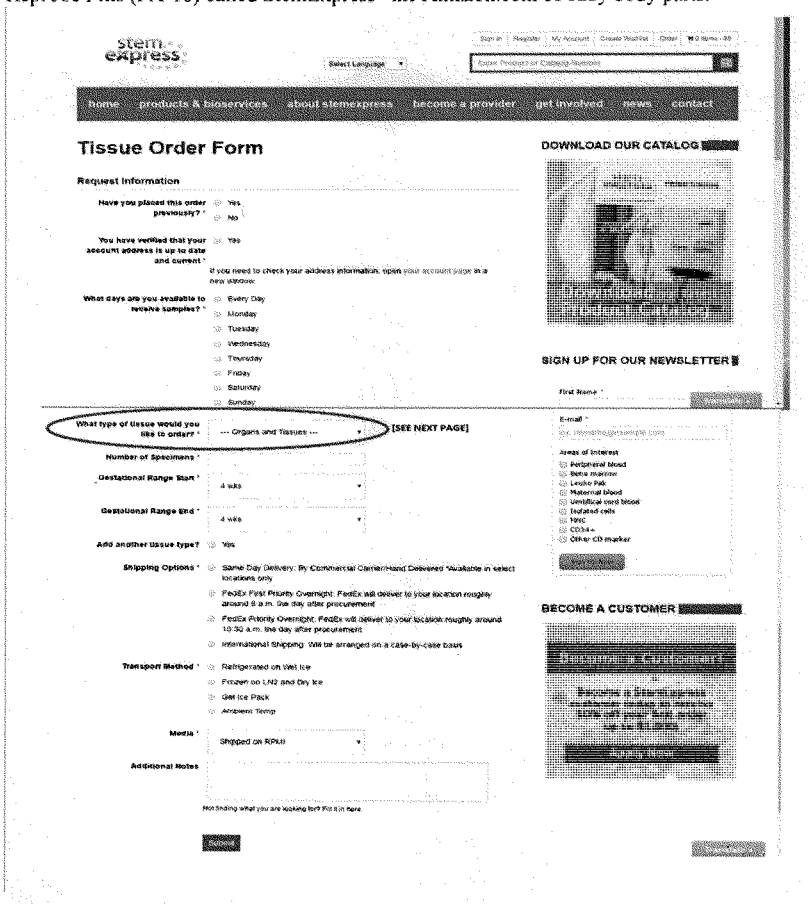
4. StemExpress Tissue Technicians Embedded in Planned Parenthood Affiliates: A Typical Day

The Panel sought to determine whether the PPFA affiliates that had contracts with StemExpress had any allowable costs under 42 U.S.C. § 289g. Documents produced by StemExpress show the clinics did not. StemExpress had tissue technicians embedded in the PPFA affiliates. The technicians obtained consent to donate fetal tissue from women scheduled to undergo abortion. They procured the fetal tissue, packaged it, and shipped it directly to StemExpress' customers. The chart below depicts the typical day of a StemExpress embedded tissue technician:

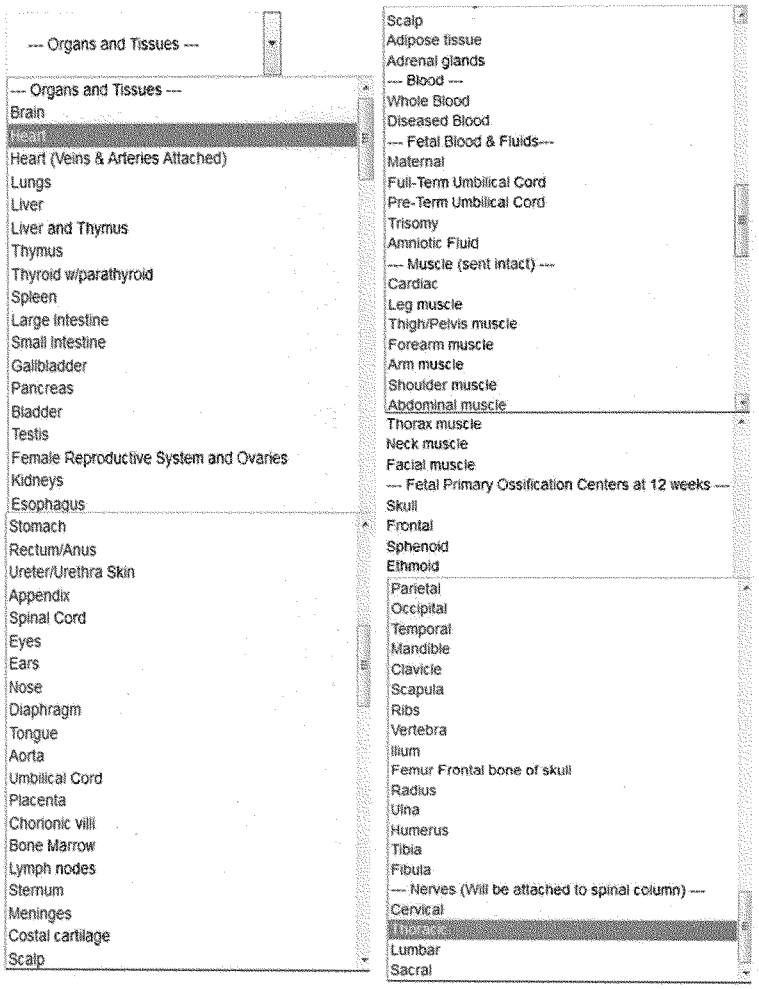


a) How Researchers Placed an Order

Customers placed orders through an on-line catalogue, a copy of which is shown below (Panel staff inserted the red circle). Based upon the web page, both Rep. Diane Black (TN-6) and Rep. Joe Pitts (PA-16) called StemExpress "the Amazon.com of baby body parts."[196]



[196] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, 114th Cong., Mar. 6, 2016 (unedited transcript 55); *The Pricing of Fetal Tissue: Hearing Before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, 114th Cong. 77 (unedited transcript) (Apr. 20, 2016).


--- Organs and Tissues ---
--- Organs and Tissues ---
Brain
Heart
Heart (Veins & Arteries Attached)
Lungs
Liver
Liver and Thymus
Thymus
Thyroid w/parathyroid
Spleen
Large Intestine
Small Intestine
Gallbladder
Pancreas
Bladder
Testis
Female Reproductive System and Ovaries
Kidneys
Esophagus
Stomach
Rectum/Anus
Ureter/Urethra Skin
Appendix
Spinal Cord
Eyes
Ears
Nose
Diaphragm
Tongue
Aorta
Umbilical Cord
Placenta
Chorionic villi
Bone Marrow
Lymph nodes
Sternum
Meninges
Costal cartilage
Scalp
Scalp
Adipose tissue
Adrenal glands
--- Blood ---
Whole Blood
Diseased Blood
--- Fetal Blood & Fluids---
Maternal
Full-Term Umbilical Cord
Pre-Term Umbilical Cord
Trisomy
Amniotic Fluid
--- Muscle (sent intact) ---
Cardiac
Leg muscle
Thigh/Pelvis muscle
Forearm muscle
Arm muscle
Shoulder muscle
Abdominal muscle
Thorax muscle
Neck muscle
Facial muscle
--- Fetal Primary Ossification Centers at 12 weeks ---
Skull
Frontal
Sphenoid
Ethmoid
Parietal
Occipital
Temporal
Mandible
Clavicle
Scapula
Ribs
Vertebra
Ilium
Femur Frontal bone of skull
Radius
Ulna
Humerus
Tibia
Fibula
--- Nerves (Will be attached to spinal column) ---
Cervical
Thoracic
Lumbar
Sacral

b) Embedded Tissue Technicians Learn of Next Day's Scheduled Abortions

The Panel sought to determine whether StemExpress employees had prior knowledge of the abortions scheduled at PPFA clinics. The Panel determined that, at the beginning of each workday, StemExpress sent an email to its tissue technicians that informed them of the scheduled abortions at the clinic to which they were assigned, listed the customer orders for fetal tissue or body parts (including the gestation requested), and described what specific tissues or parts the technicians were expected to harvest.

A document produced by StemExpress to the Panel shows that, "[t]he day before the surgery," tissue technicians were required to check the company's web-based system "for researcher requests; Determine your location for the next day; [and] Call the clinic to verify how many surgeries are scheduled."[197] The morning of the abortions, StemExpress emailed the tissue technicians the daily customer orders, including a list of the specific organs that were ordered, the desired gestational age of the organs, and other information.[198]

c) Clinic Personnel Gave Tissue Technicians Access to Patients' Private Medical Information

The Panel sought to determine whether StemExpress employees assigned to PPFA abortion clinics had access to patients' medical information that is protected under HIPAA. Testimony shows that clinic personnel provided StemExpress' embedded tissue technicians with patients' private medical records and other personally identifiable information.[199]

After StemExpress' tissue technicians arrived at their assigned sites, clinic personnel, including doctors and nurses, allowed StemExpress' tissue technicians to review the medical files of individual patients that were in files attached to the examining room doors, so they could determine whether women seeking abortions met their order specifications.[200] A person with intimate knowledge of StemExpress' operations stated on a CMP video that, often, "the head nurse gives the [tissue technicians] a sheet with a list of everyone who is coming in for that day with the types of procedures. The [tissue technicians] walk around the clinic and consent the patients, either in the waiting room or in a patient room."[201]

If, due to the large volume of patients, StemExpress tissue technicians could not review the patient files hanging on the examining room doors, clinic personnel allowed them to access clinic computer terminals that contained confidential patient medical information.[202] Doctors

[197] StemExpress, LLC, Tissue Procurement for Non-Therapeutic Research, Standard Operating Procedure (Jan. 24, 2011), Exhibit 5.19.
[198] Email from [name and title redacted], StemExpress, LLC, to [names redacted], Subject: Updated Task Assignment: Procurement Schedule Wednesday 3/20/13 (Mar. 20, 2013), Exhibit 5.20.
[199] Testimony from a confidential witness.
[200] Testimony from a confidential witness.
[201] Center for Medical Progress videotape MVI_0064 produced to the Committee on Oversight and Government Reform.
[202] Testimony from a confidential witness.

and nurses at the clinics also directed the StemExpress tissue technicians to particular patients who were good candidates for fetal tissue donations.[203]

d) Embedded Tissue Technicians Obtained Consent from Women to Donate Fetal Tissue

The Panel sought to determine whether StemExpress employees obtained consent to donate fetal tissue from women at PPFA clinics who were scheduled to undergo abortions. By her own admission to the Committee on Energy and Commerce [the Founder and CEO] stated that StemExpress employees did consent PPFA patients:

> StemExpress employee[s] can obtain consent. Once it is already determined that the patient is having an abortion, they are moved to a different waiting room, at that point [StemExpress] staff meets with the patient. If she agrees, they go over the paperwork and she signs. There are times that PPFA does the consent.[204]

Documents produced by StemExpress to the Panel show that StemExpress employees obtained consent to procure fetal tissue from patients scheduled to undergo abortions.[205] A person with intimate knowledge of StemExpress' operations stated on a CMP videotape that some StemExpress tissue technicians would procure fetal tissue specimens "without consenting patients."[206]

Unlike California PPFA clinics that had contracts with StemExpress, [PP Witness #2] testified that she would never have allowed such an arrangement at her facility. When Panel staff asked the witness whether she would have agreed to have employees of an outside vendor obtain informed consent to donate fetal tissue from PPGC patients, she testified:

> I would not agree to have outside staff come in and obtain a crucial element as the informed consent from our patient population.
>
> Q: Okay. And what is it about that that troubles you?
>
> A: I would like for only our staff to do it, because in that way we have control over their training. We have control over who is there day to day obtaining informed consents. We have control to ensure that it's done correctly, and we have the authority to follow up in the event that our procedures and our processes regarding informed consent are not followed. I would not permit a third party to come in and obtain informed consent from our patient population.[207]

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[203] Testimony from a confidential witness.
[204] *See* StemExpress Briefing Notes, Exhibit 5.14.
[205] StemExpress, LLC, Consenting Patients, undated, Exhibit 5.21.
[206] Center for Medical Progress videotape MVI_0064 produced to the Committee on Oversight and Government Reform.
[207] Transcribed interview of [PP Witness #2] at 97 (Oct. 19, 2016).

i) When it obtained consent from PPFA Affiliates, StemExpress used PPFA's consent form

The Panel sought to determine the specific form that StemExpress used to obtain consent from women scheduled to undergo abortions at PPFA affiliates. The firm produced two forms to the Panel, one that was created by PPFA, the other by StemExpress. [The Founder and CEO] told the Committee on Energy and Commerce that, when collecting fetal tissue at PPFA affiliates, StemExpress used "a PPFA consent form, which is different than the consent form at non-PPFA facilities."[208] The PPFA consent form stated, "Research using . . . tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[209]

When [PP Witness #1] was asked by the Panel whether the inclusion in the consent form of the statement that fetal tissue had been used to find a cure for incurable diseases could be construed as being coercive, the PPFA official testified: "I can understand your concern that perhaps this may make someone think about donating fetal tissue because of this potential."[210] The PPFA official testified that the wording of the PPFA consent form may make patients more likely to want to donate fetal tissue.[211]

ii) StemExpress used its own consent form when it obtained consent from patients at independent women's clinics

StemExpress had another consent form that it used at independent women's clinics. That form purported to be approved by "an institutional review board" (IRB),[212] BioMed IRB.[213] The Panel sought to determine whether BioMed IRB was a legitimate IRB. The Panel determined that it was not. In March of 2012, the FDA issued a warning letter to BioMed IRB for multiple violations of agency rules. As a result, the FDA ruled it "will withhold approval of all new studies" approved by BioMed IRB, "and [n]o new subjects are to be enrolled in any ongoing [BioMed IRB] studies . . ."[214] That ban was lifted in January 2013.[215]

Prior to the FDA suspension, the House Committee on Energy and Commerce had investigated BioMed IRB as part of an investigation into the ability of IRBs to protect human

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[208] StemExpress Briefing Notes, Exhibit 5.14.
[209] Planned Parenthood Federation of America, PPFA Manual of Medical Standards and Guidelines, Client Information and Informed Consent, Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment," Revised June 2011 [PPGC-HOU-E&C-000006], Exhibit 5.22.
[210] Transcribed interview of [PP Witness #1] (Oct. 6, 2016), at 131-132.
[211] *Id.* at 132.
[212] StemExpress Briefing Notes, Committee on Energy and Commerce (Aug. 25, 2016).
[213] BioMed IRB Informed Consent to Participate in a Clinical Research Study, Sponsor: StemExpress, LLC (Jan. 24, 2011) [STEM.HOUSE.SELECT_0680 – STEM.HOUSE.SELECT_0681], Exhibit 5.23.
[214] *See* Letter from [Compliance Official], U.S. Food and Drug Administration, to [Executive], Biomedical Research Institute of America dba BioMed IRB (Mar. 29, 2012), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm298607.htm.
[215] *Id.*

subjects in biomedical research.[216] That investigation "led the Committee to believe that the IRB application approval process is essentially perfunctory, lacking vigorous oversight and controls, and thus raising the risk of some IRBs not adequately protecting the safety of human subjects."[217]

On March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of 45 C.F.R. 46, of any entity involved with fetal tissue research or transplantation of fetal tissue for which it issued an IRB approval.[218] The BioMed IRB [Executive] informed the Panel on April 4, 2016, that, regarding StemExpress IRB records, "there are none."[219] After he refused to comply with the Panel's subpoena, [Executive] told the Panel: "Please schedule the contempt process at the earliest possible date."[220] The Panel still has yet to receive any documents from BioMed IRB.

e) StemExpress Tissue Technicians Procured the Fetal Tissue

The Panel sought to determine whether StemExpress' embedded tissue technicians or PPFA procured fetal tissue after abortions. [The Founder and CEO] told the Committee on Energy and Commerce that "StemExpress staff are the only ones procuring tissue at PPFA facilities."[221]

StemExpress produced documents about its procurement kit to the Panel that provided explicit instructions to its tissue technicians on the method to procure fetal tissue.[222] The kit included directions on the method to obtain consent from patients, to harvest body parts and fetal tissue, and to package and ship the "products" once obtained.[223] At independent abortion clinics, StemExpress tissue technicians were required to "procure the specimen(s) on the petri dish [that were included in the technicians' packages. . . ."[224]

In contracts with the PPFA affiliates with which StemExpress had contracts, [PP Witness #2] testified that she would never have allowed such an arrangement at her facility:

> A: From my ancillary knowledge of our abortion services area, it appears highly regulated. And just like the informed consent for researchers, I can't see that we would allow staff that are not or people in general that are not Planned Parenthood staff to go into the

[216] *See* Letter from Rep. John D. Dingell, Chairman, H. Comm. on Energy and Commerce, to [Executive], Biomedical Research Institute of America, et al. (Dec. 13, 2007).
[217] *See* Memorandum from Committee staff to Members and Staff Subcomm. on Oversight and Investigations (Mar. 23, 2009).
[218] *See* Subpoena to Biomedical Research Institute of America dba BioMed IRB (Mar. 29, 2016).
[219] *See* Email from [Executive], Biomedical Research Institute of America, to Panel staff (Apr. 4, 2016).
[220] *Id.*
[221] StemExpress Briefing Notes, Exhibit 5.14.
[222] StemExpress, LLC, Work Instruction, StemExpress Procurement Kit 1 (Mar. 12, 2015) [STEM.SELECT.HOUSE_0266 – STEM.HOUSE.SELECT_0272], Exhibit 5.24.
[223] *Id.*
[224] Tissue Procurement for Non-Therapeutic Research, Standard Operating Procedure, Exhibit 5.19.

> facility and be involved in the setup of the room where abortions are obtained.
>
> Q: So all of the little daily things that can go on, let's go back to consent. All the manner, the manners, the time, the thoughtfulness, understanding what you call the supplemental consent, the IRB consent, because these are staff that work directly for the clinic, you can manage them and tweak even the smallest of behaviors or practices, migrate the whole process in a direction that's under the management of you and others; is that right?
>
> A: That would be my personal preference, yes.[225]

The Panel sought to determine whether StemExpress' procurement practices were driven by a desire to assist medical researchers find potential cures for diseases or by a profit motive. StemExpress' standard operating instructions that were used at non-Planned Parenthood abortion clinics indicate it was profit. StemExpress instructed its tissue technicians:

> If you have an excellent [fetal tissue] sample with no researcher listed on today's schedule, please contact [Founder & CEO] immediately, and they will work to call researchers who may be interested even though they are not currently scheduled.[226]

i) After they procured the body parts and tissue, StemExpress employees packaged and shipped them directly to StemExpress customers

Documents produced by StemExpress to the Panel show that, along with being responsible for consent and procurement, the firm's tissue technicians also packaged and shipped the fetal tissue.

StemExpress' procurement kit provided detailed instructions on the method tissue technicians should use to package fetal tissue:

> The items of the kit should be reassembled in the same placement as they were when the kit was received.
>
> Place the specimens inside of the plastic bag liner
>
> One sealed biohazard bag with the 50ml conical tube (containing RPMI and the liver specimen) [along with] One sealed biohazard bag with 3 tubes of maternal blood (two 10ml EDTA one 5ml Z serum sep. [sic] clot activator blood collection tube) [and] 2 chilled gel packs

[225] Transcribed interview of [PP Witness #2] (Oct. 19, 2016) at 98.
[226] Tissue Procurement for Non-Therapeutic Research, Standard Operating Procedure, Exhibit 5.19.

> Seal the plastic bag liner by tying it in a knot
>
> Place the tied plastic bag inside of the Styrofoam box
>
> Place the Styrofoam lid on the Styrofoam box
>
> Adhere a biohazard sticker on opposite sides of the Styrofoam box so they seal the top of the box to the bottom.
>
> Place Styrofoam box inside the cardboard box
>
> Place completed Procurement Form on top of the Styrofoam box
>
> Tape the cardboard box shut
>
> Adhere the FedEx shipping label to the top of the cardboard box
>
> Once the package is ready for shipment call FedEx . . . to schedule a pick up or drop the package off at the nearest FedEx location by 16:30 on the day of procurement.[227]

The firm also issued its tissue technicians a four-page document on how to package and ship tissue samples.[228] StemExpress' standard operating procedure stated:

> Packaging the specimens and blood [samples] for shipment once all specimens have a number. Be sure to place them on ice or cold packs . . . . For delivery: If the specimen is local courier, be sure to call the courier once you know you have obtained an appropriate specimen. If the specimen is going by FedEx, be sure to know the local cut-off times for your closest FedEx office. Each FedEx location is listed under "contacts" in [StemExpress' web-based system].[229]

ii) StemExpress' tissue technicians had a financial incentive to procure the most body parts and fetal tissue possible

Documents StemExpress produced to the Panel indicated the tissue technicians did have such a potential conflict of interest. PPGC's research director testified that she had similar concerns.[230]

---

[227] Work Instruction, StemExpress Procurement Kit 1, Exhibit 5.24.
[228] StemExpress, LLC, Packaging Blood and Tissue Samples (Jan. 16, 2014) [STEM.HOUSE.SELECT_0257 – STEM.HOUSE.SELECT_0260], Exhibit 5.25.
[229] Tissue Procurement for Non-Therapeutic Research, Standard Operating Procedure, Exhibit 5.19.
[230] Transcribed interview of [PP Witness #2] (Oct. 19, 2016) at 162-164.

StemExpress' tissue technicians were "compensated at a rate of $10 per hour plus a per tissue or blood bonus" that varied depending upon the type of tissues and the amount they procured. The document produced by StemExpress is below.[231]

stem express

Procurement Technician Compensation Policy for Tissue and Blood Procurement Effective 01/01/2013

Procurement Fees

- Procurement Technicians are compensated at a rate of $10.00 per hour plus a per tissue or blood bonus as outlined in the table below:

Tissue Bonus Structure			
# Specimens	Category A*	Category B*	Category C
1-10 Specimens	$35/Tissue	$15/Tissue	$10/Blood
11-20 Specimens	$45/Tissue	$20/Tissue	$15/Blood
21-30 Specimens	$55/Tissue	$25/Tissue	$20/Blood
31-40 Specimens	$65/Tissue	$30/Tissue	$25/Blood
41-50 Specimens	$75/Tissue	$35/Tissue	$30/Blood

*Blood Samples may be obtained with these specimens in which case Category C bonus does not apply.

Please refer to the Procurable Specimens by Category dated 01/01/2013 for a detailed listing of Tissues.

Two or More Procurement Technicians working in Unison

- Procurement Technicians often work in unison so procurements are split equality between the technicians.

For example, If two technicians are working together at the same clinic, and two maternal bloods are procured, each technician would receive $5 for the Blood Procurement.

778 Pacific Street / Placerville CA 95667
T: 530-626-7000 F: 530-26-7900 / info@stemexpress.com / www.stemexpress.com

HIGHLY CONFIDENTIAL INFORMATION / NOT FOR PUBLIC RELEASE STEM.HOUSE.SELECT_ 0672

[231] StemExpress, LLC, Procurement Technician Compensation Policy for Tissue and Blood Procurement Effective 01/01/2013 [STEM.HOUSE.SELECT_0672 – STEM.HOUSE.SELECT_0674].

Procurable Specimens by Category
Effective 01/01/2013

Category A*
Brain
Heart
Lungs
Liver
Thymus
Thyroid w/parathyroid
Liver
Spleen
Large Intestine
Small Intestine
Gallbladder
Pancreas
Bladder
Testis
Ovaries
Esophagus
Stomach
Rectum/Anus
Ureter/Urethra
Appendix
Spinal Cord
Spinal Column
Eyes
Diaphragm
Lymph nodes
Sternum
Adipose tissue
Lymph nodes
All Muscle tissue
All Bone structures

Category B*
Kidneys
Adrenal glands
Ear
Decidua
Chorionic Villi
Umbilical Cord
Placenta
Amniotic Fluid
Large Intestine
Small Intestine
Skin
Nose
Tongue
Scalp

Category C
Maternal Blood
Post Surgery Blood
Umbilical Cord Blood
Trisomy Blood

*Note: Blood Samples may be obtained with these specimens in which case Category C bonus does not apply

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The Panel sought to determine whether StemExpress' payment rate was standard practice at abortion clinics which participated in fetal tissue donation programs. The Panel found it was not. When [PP Witness #2] was asked whether she would allow tissue technicians employed by an outside firm, who were reimbursed by the outside firm based on the amount of tissue they procured, into her facility, she testified, "That's not something I would initiate in our organization, no."[232]

The Panel determined that the PPFA affiliates at which StemExpress procured fetal tissue had no allowable costs under 42 U.S.C. § 289g. StemExpress' embedded tissue technicians obtained consent to donate fetal tissue from women scheduled to undergo abortion, procured the fetal tissue, packaged it, and shipped it directly to StemExpress' customers. Thus, the Panel determined the PPFA affiliates had no allowable costs.

5. StemExpress' Due Diligence

The Panel sought to evaluate StemExpress' level of due diligence before entering into contracts with the independent abortion clinics at which it procured fetal tissue. The Panel discovered StemExpress failed to examine the disciplinary records of officials and doctors at those independent clinics.

The director of one clinic, and doctors at others, were disciplined multiple times by state regulators. In addition, multiple clinic doctors settled malpractice suits. Panel staff found these issues through simple online searches, which raises the question of whether StemExpress did any background checks on the clinics or doctors with which it did business.

At Camelback Family Planning, the clinic official who signed the contract with StemExpress had multiple disciplinary proceedings for substance abuse, two of which occurred before she signed the StemExpress signed contract. Even though she performed abortions, the doctor was not an Ob/Gyn. The doctor surrendered her license to practice medicine.

The Presidential Women's Specialists clinic settled four malpractice suits, including one that involved a woman who died five days after an abortion surgical instruments were left inside her body. Three of the clinic's doctors have either been disciplined by the state department of health, including performing an abortion on a 12-year-old girl (which is below the age of consent in the state), destroying evidence related to that case, and not informing law enforcement of child abuse. The state charged the same doctor with gross or repeated malpractice involving another patient.

One doctor who performs abortions at Cedar River Clinics has been disciplined by the state, and another settled a malpractice suit that alleged that he had to perform an emergency hysterectomy after he perforated the patient's uterus during an abortion.

---

[232] Transcribed interview of [PP Witness #2] at 114-15 (Oct. 19, 2016).

6. Payments Received by Clinics

Between 2010 and the middle of 2015, StemExpress paid the clinics from which it procured fetal tissue a total of $152,460. Between 2010 and the middle of 2015, StemExpress paid the clinics a total of $366,443 for both blood and fetal tissue.[233] StemExpress produced over a hundred monthly invoices from PP affiliate clinics. Stem refused to produce invoices for other clinics from which it procured fetal tissue. The Panel sought those invoices directly from those clinics. StemExpress paid the following amounts for fetal tissue. These numerical sums are calculated by the Panel's forensic accountant from these invoices:

- $123,175 to Planned Parenthood Mar Monte
- $12,705 to Planned Parenthood Shasta Pacific
- $8,130 to Family Planning Services
- $4,875 to Presidential Women's Center
- $2,375 to Cedar River Clinics
- $1,200 to Camelback Family Planning.

Over the same time period (2010 through the middle of 2015), StemExpress paid the clinics a total of $213,983 for blood draws. StemExpress produced over a hundred monthly invoices from Planned Parenthod affiliate clinics. StemExpress refused to produce invoices for other clinics from which it procured fetal tissue. The Panel sought those invoices directly from those clinics. These numerical sums are calculated by the Panel's forensic accountant from these invoices.

StemExpress paid:

- $100,143 to Planned Parenthood Mar Monte
- $88,625 to Cedar River Clinics
- $10,905 to Presidential Women's Center
- $7,750 to Planned Parenthood Shasta Pacific
- $6,415 to Family Planning Services for blood.

[233] Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, Planned Parenthood of Santa Barbara, Ventura & San Luis Obisbo Counties, Camelback Family Planning, Cedar Rivers Clinics, Family Planning Specialists Medical Group. Presidential Women's Center, and Women's Health Specialists produced to the Panel documents that reflected payments the entities had received from StemExpress, LLC. Panel staff conducted a forensic accounting analysis of those payments to determine the total amounts to the entities.

During the course of its investigation, the Panel sought to determine the motive of clinic executives when they entered into their contracts with StemExpress. In at least one instance, an executive from a clinic at which StemExpress procured fetal tissue indicated that profit may have been a motive. [Clinic Executive #1] stated to CMP journalists that the clinic made approximately $250,000 a year from fetal tissue and blood donations:

> [Clinic Executive #1]: [Laughter] Well, I just—we've been into this, and it's been very good. And now we've gone through our first year—
> CMP journalist: Yeah.
> [Clinic Executive #1]: I mean, I was looking at numbers of, you know, $250,000 a year. And now—
> CMP journalist: I'm sorry, say that again?
> [Clinic Executive # 1]: I mean, originally, we were looking at numbers of about $250,000 a year. Last year I did $100,000.[234]

The Panel notes that, in most instances, the clinics had little or no allowable reimbursable costs as permitted under § 289g-2.

7. Payments Received by StemExpress for Its Resale of Fetal Tissue

StemExpress produced invoices that it sent to customers. The numerical sums listed below are calculated by the Panel's forensic accountant from these invoices. Invoices produced to the Panel by StemExpress show that, between 2011 and 2016, StemExpress received a total of $593,152 in payments from its customers. The invoices show the total payments from customers included $59,300 in payments for disease screening and $53,110 for the shipment or delivery of fetal tissue products.

The Panel notes that, in addition to fresh fetal tissue and body parts, StemExpress sold products derived from fetal tissue. The invoices produced by StemExpress to the Panel do not reflect the sale of products derived from fetal tissue.

Below is a chart of StemExpress' customers, and the amounts the customers paid the firm (all amounts are in U.S. dollars).

[234] Center for Medical Progress, videotape FNND0569_20150419153726 (Apr. 7, 2014) produced to the Committee on Oversight and Government Reform.

CLIENT	2011	2012	2013	2014	2015	2016	GRAND TOTAL
AllCells, LLC.	73,045	7,720	4,880				85,645
Baylor College of Medicine		5,785	1,630				7,415
Beckman Research Institute City of Hope			545	760			$2,065
Children's Hospital of Philadelphia					695	695	1,390
Columbia University Medical Center	615	3,715	995				5,325
Colorado State University	3,835	1,645	2,930				8,410
Dartmouth University	3,920	5,010	585				9,515
Drexel University College of Medicine	3,680						3,680
Ganogen, Inc.			6,535	805			7,340
George Washington University		350					350
Harvard University			8,610				8,610
Howard Hughes Medical Institute	340	695					1,035

Johns Hopkins Hospital	1,950	1,680					3,630
Massachusetts General Hospital		4,560	10,705				15,265
Medical College of Wisconsin				2,740			2,740
Neurona Therapeutics					1,830		1,830
Ohio State University	490						490
Rockefeller University			855				855
Stanford University	37,940	42,739	18,050	57,070	27,190		182,989
Thomas Jefferson University			500				500
University of California. Los Angeles	3,920	8,920	9,000				21,840
University of Connecticut Health Center	780	1,700	500				2,980
University of Illinois at Chicago		335	820				1,155
University of Massachusetts Medical School	62,275	62,195	23,705	2,159	491		150,825

University of Minnesota				3,235			
University of North Carolina, Chapel Hill		720	1,835				2,555
University of Pennsylvania			4,790				4,790
Vanderbilt University Medical Center	11,955	9,665	5,640	845		-125	
Yale University School of Medicine	515	12,065					12,580
Zyagen	5,080				3,570		8,659
TOTAL ALL CUSTOMERS							**$593,152**

8. The Select Panel Recommends that the House Find StemExpress in Contempt of Congress

For nearly a year, the Panel sought documents, including accounting documents, from StemExpress.[235] In its first response to the Panel's document request, StemExpress provided very limited information. StemExpress produced a general accounting summary that stated: "[F]etal tissue procured from Planned Parenthood Affiliates generated approximately $50,000 in gross (pre-tax) revenue against expenses in excess of $75,000."[236]

As a result of StemExpress' limited compliance with the Panel's document request letter, the Chairman, over a three-month period, issued two subpoenas to StemExpress,[237] one to the founder & CEO,[238] and another to StemExpress' outside accountant, Scinto Group, LLP (Scinto).[239]

[235] Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [Founder and CEO, StemExpress, LLC] (Dec. 17, 2015), Exhibit 5.1.1.
[236] StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016), Exhibit 5.2.
[237] Subpoena to StemExpress, LLP, (Feb. 12, 2016), Exhibit 5.3.
[238] *See* Subpoena to [Founder & CEO] (Mar. 29, 2016).
[239] *See* Subpoena to Scinto Group, LLP (Apr. 29, 2016)

[The Founder and CEO] refused to comply with the Panel's March 29, 2016, subpoena.[240] Like the Panel's February 12, 2016, subpoena to StemExpress, the subpoena issued to [the Founder and CEO] requested the names of StemExpress accounting personnel and documents showing accounts payable and receivable.[241] [The Founder and CEO] refused to provide any of the information demanded by the Panel's subpoena.

In addition, she suggested that the Panel seek the information it required from Scinto or from [Former StemExpress Employee]. Once again, attorneys for [the Founder and CEO] offered summary documents of revenue and costs, but no accounting records.[242] [The Founder & CEO]'s and StemExpress' counsel, who also represented [Former StemExpress Employee], explained that [Former StemExpress Employee] had only W-2's and related tax information. For her part, [Former StemExpress Employee] told Panel staff that she had no documents and that if the Panel contacted her again she would consider it harassment.[243]

Scinto refused to comply with the Panel's subpoena and to date has provided no accounting documents. Scinto told the Panel that StemExpress objected to Scinto's compliance with the Panel's subpoena on the grounds of several privileges.[244] The Panel informed Scinto that its objections based upon the asserted privileges were inapplicable and do not impair the legal requirement to comply with a congressional subpoena.[245] Despite these efforts, Scinto refused to comply with the Panel's subpoena.[246]

On August 23, 2016, McDermott Will & Emery, the law firm previously representing StemExpress and [the Founder and CEO] throughout the course of the investigation, informed the Panel that StemExpress was no longer their client.[247] StemExpress' former attorney supplied the Panel with contact information for the new lawyer.[248] On September 8, 2016, Chairman Blackburn sent a letter to Mr. Frank Radoslovich, the new counsel for StemExpress, and [the Founder and CEO], outlining a brief history of the Panel's interactions with StemExpress, and

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[240] StemExpress First Response to House Select Panel's March 29, 2016 Subpoena [STEM.HOUSE.SELECT_0713 – STEM.HOUSE.SELECT_0715], Exhibit 5.26.
[241] *See* Subpoena to [Founder & CEO] (Mar. 29, 2016).
[242] StemExpress First Response to House Select Panel's March 29, 2016 Subpoena [STEM.HOUSE.SELECT_0713 – STEM.HOUSE.SELECT_0715], Exhibit 5.26.
[243] *See* Memorandum from House Select Investigative Panel Counsel to Majority Members of the House Select Investigative Panel (Mar. 7, 2016).
[244] Letter from Kevin Murphy, Carr Maloney LLP, to T. March Bell, Chief Counsel and Staff Director, Select Investigative Panel on Infant Lives [sic] (Sept. 16, 2016), Exhibit 5.1.6.
[245] *See* T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel, to Kevin Murphy, Carr Maloney LLP (Sept. 8, 2016), Exhibit 5.1.5
[246] Letter from Kevin Murphy, Carr Maloney LLP, to T. March Bell, Chief Counsel and Staff Director, Select Investigative Panel on Infant Lives [sic] (Sept., 16, 2016), Exhibit 5.1.6 (" . . . if not for the potential application of the privilege and/or confidentiality laws, Scinto Group LLP would be willing and able to comply with a valid subpoena from the Select Investigative Panel. However, in light of the potential application of those laws, under the current circumstances, Scinto Group is not in a position to unilaterally respond to the subpoena with the requested documents, absent client consent.").
[247] *See* Email from Amandeep S. Sidhu, McDermott Will & Emery, to Panel Staff (Aug. 23, 2016).
[248] *Id.*

the Panel's unsuccessful attempts to reach an accommodation with StemExpress.[249] The letter concluded:

> Since StemExpress has been unwilling to comply with the Panel's subpoenas and having exhausted all its efforts to obtain compliance from the subpoena recipients, the Chairman of the Select Investigative Panel will recommend that StemExpress and [StemExpress Founder and CEO] be held in contempt for their willful failure to fully comply with the Panel's subpoena issued to them . . . .[250]

The Chairman provided one last opportunity for StemExpress and [the Founder and CEO] to comply with the subpoenas.[251] In April 2016, the Panel wrote a letter to [the Founder and CEO] that included a chart of the missing items in an attempt to secure compliance with the congressional subpoenas.[252] In a response letter, former counsel for StemExpress and [the Founder and CEO] disputed the Panel's attempt to clarify what was missing.[253] After receiving no substantive reply from StemExpress' new counsel, the Panel, on September 21, 2016, voted unanimously to recommend that the House of Representatives hold StemExpress and [the Founder and CEO] in contempt of Congress.[254]

9. StemExpress May Have Violated Federal Laws and Regulations

H. Res. 461 required the Panel to undertake an investigation into "medical procedures and business practices used by entities involved in fetal tissue procurement . . . and any changes in law or, regulation necessary resulting from" its investigation.[255]

The Panel, acting pursuant to H. Res. 461, determined that StemExpress may have violated applicable federal and state laws, and regulations promulgated by the Department of Health and Human Services. The Panel referred StemExpress' apparent violations of laws to appropriate federal and state law enforcement and violations of regulations to the appropriate agency. (See Chapter IV for a discussion of the criminal referrals made by the Panel.)

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[249] *See* Letter from Rep. Marsha Blackburn, Chairman, Select Investigative Panel, to Frank Radoslovich, counsel for StemExpress (Sept. 8, 2016), Exhibit 5.1.7.
[250] *Id.*
[251] *Id.*
[252] *See* Letter from Rep. Marsha Blackburn, Chairman, Select Investigative Panel, to [Founder and CEO], StemExpress, LLC (Apr.28, 2016), Exhibit 5.1.8.
[253] *See* Letter from Amandeep S. Sidhu, McDermott Will & Emery, to Rep. Marsha Blackburn, Chairman, House Select Investigative Panel (May 6, 2016), Exhibit 5.1.9
[254] *See* Select Investigative Panel of the H. Comm. on Energy and Commerce, Business Meeting, unedited transcript, Sept. 21, 2016.
[255] H. Res. 461 (Oct. 7. 2015).

d) 18 U.S.C. § 1519

18 U.S.C. § 1519 makes it a 20-year felony for "Whoever knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any department or agency of the United States . . . ."[256]

The Panel determined that StemExpress may have violated 18 U.S.C. § 1519 by potentially destroying documents pertinent to congressional investigations into the fetal tissue industry, including documents that were covered by the Panel's subpoenas. The Panel's two subpoenas to StemExpress direct that "No records, documents, data or information called for by this request shall be destroyed, modified, removed, transferred or otherwise made inaccessible to the Select Panel."[257]

StemExpress' bank produced to the Panel banking records that show StemExpress payments to Shred-It USA that, for the most part, correspond with dates of document demand letters from congressional investigations of the fetal tissue industry, subpoenas from the Panel, and StemExpress productions to the Panel and other congressional inquiries. StemExpress bank records dating back to November 2012 reveal there were no payments made to Shred-It USA prior to the first congressional investigations into the fetal tissue industry. Since the first congressional inquiries began, and continuing through the Panel's investigation, StemExpress made payments to Shred-It USA.

The Panel cannot determine what specific documents StemExpress shredded, but the timing raises the question of whether StemExpress knowingly and willfully attempted to avoid productions to a congressional inquiry.

e) 42 U.S.C. § 289g-2

42 U.S.C. § 289g-2(a) states, "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Under that law, "the term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[258] Human fetal tissue is defined broadly to include any "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth."[259]

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[256] 18 U.S.C. § 1519.
[257] Subpoena to StemExpress, LLP, (Feb. 12, 2016), Exhibit 5.3; Instructions Item 5 (Mar. 29, 2016).
[258] 42 U.S.C. § 289g-2(e)(3).
[259] 42 U.S.C. § 289g-1(g).

f) California Health and Safety Code Section 125320

The California Health and Safety Code contains virtually identical language as 42 U.S.C. § 289g-2. That law states that:

> (a) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.
>
> (b) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.
>
> (c) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.[260]

As with § 289g, another provision of the California Health and Safety Code broadly defines tissue to "mean a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body . . ."[261]

The Panel determined that StemExpress may have violated 42 U.S.C. § 289g-2 and Cal. Health & Safety Code § 125320(a). This can be seen generally by the company's aggressive growth strategy, which explicitly included the goal of generating profit, and specifically by the transactions involving the transfer of fetal tissue to and from numerous entities for consideration that exceeded statutorily allowable costs.

g) HIPAA

The HIPAA privacy rule is described in detail in Chapter II. The Panel determined that StemExpress may have committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. StemExpress did not have a medically valid reason to see patients' PHI. StemExpress' contracts with PPFA affiliates contend that the tissue procurement firm was a business associate. That statement does not comport with HIPAA or with CRS' interpretation of the statute.

h) HHS Regulations on Informed Consent

The Department of Human Service regulations that require researchers to obtain informed consent from each human being used as a research subject, and that outline the elements of informed consent that shall be provided to each subject are described in detail in Chapter III: Panel Hearings.

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[260] Cal. Health & Safety Code § 125320.
[261] Cal. Health & Safety Code § 1635(c).

The Panel has determined that StemExpress may have violated the HHS regulations on informed consent. When it obtained informed consent from patients at PPFA affiliates, StemExpress used the PPFA consent form, which states that fetal tissue has been used to cure diseases. For example, the PPFA consent form used by Planned Parenthood Los Angeles states, "Research using . . . tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[262]

Numerous witnesses, including senior PPFA officials, testified before the Panel that the PPFA consent form is misleading and unethical due to its contention that fetal tissue has been used to find a cure for diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS. [PP Witness #1] testified that the PPFA consent form contained inaccurate statements, and that she, the person who oversees the production of the PPFA manual that contains the consent form, was not happy that an inaccurate document was in the manual:

> Q: Have we found a cure for cancer?
> A: If we had found a cure, we wouldn't be asking for tissue donations to try to find a cure.
> Q: Have we found a cure for AIDS?
> A: Not that I'm aware of, not yet.[263]

> [A:] . . . To my knowledge there is no cure for AIDS. So that is probably an inaccurate statement . . . . a consent form should not have an incorrect statement [on it].[264]

i) HHS Regulations on Coercion

The HHS regulations further state: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as . . . pregnant women . . . additional safeguards" are included.[265]

The Panel sought to determine whether StemExpress coerced women who underwent abortions. The Panel determined that such coercion on the part of StemExpress may have occurred. For example, emails produced by StemExpress to the Panel show that its tissue procurement technicians engaged in real-time email correspondence with researchers while abortions were taking place—presumably before they obtained informed consent to procure fetal tissue—and yet StemExpress employees already were promising to deliver fetal tissue.

On January 22, 2015, at 12:26 p.m., a customer emailed a StemExpress employee stating: "Just wanted to check in and see if there are any cases within our gestation range for today?

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[262] Planned Parenthood Consent Form, Exhibit 5.22.
[263] Unedited transcribed interview of [PP Witness #1] at 130 (Oct. 6, 2016).
[264] Unedited transcribed interview of [PP Witness #1] at 131 (Oct. 6, 2016).
[265] 45 C.F.R. § 46.111(7)(b).

Need to book some time on the equipment if so."[266] Within minutes, at 12:30:11 p.m., the StemExpress employee replied: "There is one case currently in the room, I will let you know how the limbs and calvarium [skull] look to see if you are able to take them in about fifteen minutes."[267] Less than two minutes later, the customer wrote: "Great thank you so much."[268] At 1:20:32 p.m., the StemExpress employee informed the customer:

> The calvarium is mostly intact, with a tear up the back of the suture line, but all pieces look to be there. The limbs, one upper and one lower, are totally intact, with one upper broken at the humerus, and one lower broken right above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply.[269]

Approximately five minutes later, the customer replied: "That sounds great we would like both of them. Please send them our way. Thanks again . . ."[270] The StemExpress employee responded: "Limbs and calvarium will be there between 3:30 and 4:00."[271]

[PP Witness #1] testified before the Panel that the PPFA consent form used by Novogenix may coerce women to donate fetal tissue. When she was asked whether the "incorrect statement" that fetal tissue has found a cure for various diseases "could be viewed as coercive or . . . more likely to induce somebody to want to donate fetal tissue," the PPFA executive testified: "I can understand your concern that perhaps this may make someone think about donating fetal tissue because of this potential."[272]

j) HHS Regulations on Institutional Review Boards

HHS regulations require IRBs to "prepare and maintain adequate documentation" of their activities, including copies of all research proposals reviewed, scientific evaluations of those proposals, minutes of IRB meetings, records of continuing review activities, and copies of all correspondence between the IRB and the investigators.[273] The HHS IRB regulations only cover investigations of products regulated by the Food and Drug Administration.[274]

The Panel sought to determine whether any of the fetal tissue procured by StemExpress and resold to researchers was used in any product regulated by the FDA. The Panel could not make such a determination due to the lack of documentation provided by StemExpress.

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[266] StemExpress, LLC, purchase order and emails [STEM.HOUSE.SELECT_0369 – STEM.HOUSE.SELECT_0382], Exhibit 5.27.
[267] *Id.*
[268] *Id.*
[269] *Id.*
[270] *Id.*
[271] *Id.*
[272] Unedited transcribed interview of [PP Witness # 1] at 131-32 (Oct. 6, 2016).
[273] 45 C.F.R. § 46.115(a).
[274] 21 C.F.R. § 56.101(a).

The Panel sought to determine whether BioMed IRB, which StemExpress represented approved its research, complied with 45 C.F.R. 46. By its own admission, BioMed IRB violated the HHS regulations by it representation to the Panel that it had no records that related to StemExpress.

The Panel, as a result, determined that StemExpress may have violated 45 C.F.R. 46 through statements that the firm provided abortion clinics with IRB Certified Consents, and that "Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines." Those representations appeared on brochure distributed at the NAF meetings.

k) California Revenue and Tax Code

A provision of the California Revenue and Tax Code states:

> [E]very retailer engaged in business in this state and making sales of tangible personal property for storage, use, or other consumption in this state, not exempted . . . shall, at the time of making the sales or, if the storage, use, or other consumption of the tangible personal property is not then taxable hereunder, at the time the storage, use, or other consumption becomes taxable, collect the tax from the purchaser and give to the purchaser a receipt therefore in the manner and form prescribed by the [California State Equalization Board].[275]

The law defines a "retailer engaged in business in" California as "Any retailer maintaining, occupying, or using, permanently or temporarily, directly or indirectly, or through a subsidiary, or agent, by whatever name called, an office, place of distribution, sales or sample room or place, warehouse or storage place, or other place of business."[276]

There is an exemption for the sale of human blood and human body parts.[277] StemExpress is not a tissue or blood bank; rather, it sells fetal tissue cells, cell lines, and other products directly to customers. The California State Board of Equalization (SBE) recently collected nearly $82,000 for unpaid sales taxes for a non-profit organization that saves dogs, draws blood from those dogs, and sells the white blood cells, plasma, and red blood cells for transfusions into other canines.[278]

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[275] Cal. Rev. & Tax Code § 6203. A publication put out by the State Board of Equalization ("SBE") states that provision applies to corporations, individuals, Limited Liability Companies, Limited Liability Partnerships, Limited Partnerships, partnerships, married co-owners, registered domestic partnerships, and organizations. *See* Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, at 1 (May 2014).

[276] Cal. State Bd. of Equalization, "Laws, Regulations & Annotations, Sales and Use Tax Law, Chapter 3. The Tax," https://www.boe.ca.gov/lawguides/business/current/btlg/vol1/sutl/6203.html.

[277] Cal. Rev. & Tax Code § 33 ("Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.").

[278] Chris Haire, "Greyhound Dog Rescue Hemopet Fights to Stay Open after $82,000 Tax Bill," *Orange County Register*, Oct. 10, 2016, http://www.ocregister.com/articles/blood-731674-hemopet-greyhounds.html.

The statute defines tangible personal property as "personal property which may be seen, weighed, measured, felt, or touched, or which is in any other manner perceptible to the senses."[279] Thus, cells and cell lines are tangible personal property under the California Sales and Use Tax.

An SBE publication states that California companies can pass along the amount of sales tax to customers, provided the business lists a separate amount for sales tax reimbursement on its receipts or invoices, or if the sales agreement "specifically calls for the addition of sales tax reimbursement."[280] If the business includes sales tax reimbursement in its prices, companies "must inform the buyer that tax is included" by making one of the following statements on a price tag or in an advertisement: "All prices of taxable items include sales tax reimbursement computed to the nearest mill," or "The price of this item includes sales tax reimbursement to the nearest mill."[281] Neither of those statements are on StemExpress' website, nor in any advertisements or brochures produced to the Panel.

Under the California Revenue and Tax Code:

> Internet sales are treated just like sales made at retail stores, by sales representatives, over the telephone, or by mail order. If your business is located in California, retail sales of tangible personal property that you make over the Internet to California customers are generally taxable unless the sales qualify for a specific tax exemption or exclusion . . . and you are required to register for a permit and report and pay tax to the same extent as any other retailer in California.[282]

The Panel sought to determine whether StemExpress complied with the California Revenue and Tax Code. The Panel has determined StemExpress may have violated that statute because it did not charge the legally required sales tax to its California-based clients.

10. The Panel Makes Criminal Referrals Based on StemExpress' Apparent Violations of Law and Federal Regulations

The Panel sent criminal referrals that allege StemExpress may have violated applicable federal and state laws, and federal regulations to the following authorities:

- The U.S. Attorney General related to potential violations by StemExpress of 18 U.S.C. § 1519 and 42 §289g-2.

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[279] Cal. Rev. & Tax Code § 6016.
[280] Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, at 5 (May 2014).
[281] *See id.*
[282] Cal. State Bd. of Equalization, "Publication 109 Internet Sales" 5, https://www.boe.ca.gov/formspubs/pub109/.

- The El Dorado County, California, District Attorney related to potential violations by StemExpress of the California Health and Safety Law, and the California Tax Revenue and Tax Code.

- The U.S. Department of Health and Human Services related to potential violations of the Health Insurance Portability and Accountability Act of 1996.

- The U.S. Department of Health and Human Services related to potential violations 45 C.F.R. 46.

B. DaVinci Biosciences, LLC/DaVinci Biologics, LLC: A Case Study

7. Summary

Documents obtained by the Panel and a lawsuit filed by the Orange County, California District Attorney[283] suggest that DaVinci Biosciences, LLC (DaVinci), and DaVinci Biologics, LLC (DVB) were driven by one motive: profit. Documents cited in the District Attorney's lawsuit show that DaVinci and DVB charged considerably more for fetal tissue and cell lines derived from that tissue than the costs it incurred. The firms' business and marketing plans show that officers and directors pushed their employees to sell more and more tissue, and thus increased DaVinci and DVB's bottom line. The company's sole source of fetal tissue was at Planned Parenthood of Orange and San Bernardino Counties.

The Panel has uncovered evidence that DaVinci and DVB may have violated 42 U.S.C. § 289g-2 and provisions of the California Health and Safety Law and the California Tax Revenue and Tax Code.

c) Background of DaVinci and DVB

DaVinci was founded as a for-profit corporation with the California Secretary of State on December 19, 2007.[284] DVB was also founded as a for-profit corporation and filed its incorporation papers with the California Secretary of State on March 16, 2009.[285] DVB was and remains located at the same physical location as DaVinci.[286] The California Franchise Tax Board revoked DaVinci's powers, rights, and privileges on July 28, 2015.[287] It took the same action against DVB on November 3, 2014.[288]

Such revocations occur when an entity fails to do the following: File a tax return; Pay taxes or penalties (including any to the Secretary of State penalty); Pay fees (such as collection,

[283] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[284] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov.
[285] *Id.*
[286] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[287] *Id.*
[288] *Id.*

filing enforcement, lien, sheriff, or exempt fees); or Interest. "Suspended business entities lose their rights, powers, and privileges to conduct business in California."[289] The Orange County District Attorney alleged the Franchise Tax Board revoked DaVinci and DVB's ability to conduct business in California because the firms failed to pay all the required taxes or fees.[290] Documents produced by DVB show that, despite its revocation, the firm continued to conduct business through October 16, 2015.[291]

The counsel for both entities informed the Panel that "DVB is a subsidiary of DaVinci Biosciences, LLC."[292] DaVinci is jointly owned and managed by [DVB Executives].[293] [DVB Executive #1] is a founding member of both DaVinci and DVB.[294] The other founders of both DaVinci and DVB are [DVB Executives #2 and #3].[295] All are related.[296]

d) History of the Panel's Interactions with DaVinci and DVB

The Panel sent a December 18, 2015 document request letter to DVB that asked for, among other items, a list of all entities from which it procured fetal tissue and to which is sold or donated fetal tissue, an organization chart, all communications that direct DVB personnel to procure fetal tissue, and all accounting and banking records.[297]

DVB responded in a January 29, 2016 letter in which it produced only information about where it procured fetal tissue, a list of entities to which it sold or donated fetal tissue, and an organization chart.[298] DVB in that same letter agreed to produce on a rolling basis all communications that direct its personnel to procure fetal tissue, all accounting records, all specific requests for fetal tissue made by any entity (including order lists, billing records, and payment records), documents related to equipment (including maintenance costs and depreciation), an inventory of all fetal tissue procured or sold, and its banking records.[299]

On May 5, 2016, the Panel issued a subpoena to DVB that required the production by May 23, 2016, of all the documents requested in the December 18, 2015, letter, as well as detailed accounting records, copies of invoices that related to the sale of fetal tissues or cell lines derived therefrom, and communications or documents related to Institutional Review Board

[289] State of California Franchise Tax Board website, https://www.ftb.ca.gov/businesses/faq/742.shtml.
[290] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[291] Invoices produced to the Panel by DaVinci Biologics, LLC (May 27, 2016).
[292] *See* Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel (Jan. 29, 2016).
[293] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[294] *Id.*
[295] *Id.*
[296] *Id.*
[297] *See* Letter from Rep. Marsha Blackburn, Chair, Select Investigative Panel, to Juan Jose Duran, Vice President for Operations, DaVinci Biologics, LLC (Dec. 18, 2015).
[298] *See* Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel (Jan. 29, 2016).
[299] *See id.*

approvals.[300] The subpoena did not demand the production of charitable contributions made by DVB, its officers, or executives.[301]

During a May 13, 2016, telephone conference with Panel staff, DVB offered to produce various accounting documents, with the provision that the Panel's forensic accountant would review the documents.[302] If the Panel determined that the documents were inadequate, the Panel could request more detailed records.[303] On May 18, 2016, DVB produced cost analysis and other financial documents that it contended showed the firm lost money on fetal tissue production and sales.[304] After a forensic accounting analysis of the proposed production, the Panel found that the documents were insufficient to determine the adequacy of the applicable federal statute.

On May 27, 2016, DVB produced to the Panel 1,711 invoices that counsel for the firm represented covered all orders for fetal tissue.[305] DVB still has not produced all communications related to the procurement or sale of fetal tissue, accounting memoranda, chart of accounts, tax returns, bank statements, orders for fetal tissue, and communications and documents that relate or refer to Institutional Review Board approvals.

In late May 2016, the Panel discovered an online copy of the Planned Parenthood Orange and San Bernardino Counties' (PPOSBC) 2008-2009 program report which listed DaVinci as having donated between $1,000 and $2,499 to the Planned Parenthood affiliate.[306] Panel staff held a May 26, 2016, telephone conference with DVB counsel to request information on DVB's charitable contributions to PPOSBC from January 1, 2010, through May 26, 2016. In a June 7, 2016, email to staff, DVB's counsel represented that DVB:

> only made two donations to PPOSBC during this time period, which together totaled only $380. The donations were made by purchasing a ticket (at a price of $190) to attend PPOSBC's annual fundraising luncheon. We trust you'll find that these donations were nominal and hardly represented some sort of effort by DV Biologics to covertly pay PPOSBC for fetal tissue donations it received.[307]

Panel staff and DVB counsel exchanged emails on June 7, 2016, in which the Panel requested additional information and documentation.[308] In a June 9, 2016 email to the Panel, DVB counsel produced records that show DVB officials donated a total of $3,030 to PPOSBC,

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[300] Subpoena to DV Biologics, LLC (May 5, 2016), Exhibit 5.29.
[301] *Id.*
[302] Telephone conference between Panel staff and R. Joseph Burby, IV, Bryan Cave LLP (May 13, 2016).
[303] *See* Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel (Jan. 29, 2016). Telephone conference between Panel staff and R. Joseph Burby, IV, Bryan Cave LLP (May 13, 2016).
[304] *See* Letter from Michael R. Tein, co-counsel to DVB, to Panel staff (May 16, 2016).
[305] *See* Email from Matthew Simmons, Lewis Tein PL, to Panel staff (May 27, 2016).
[306] *See* Planned Parenthood of Orange and San Bernardino Counties, "Program Report 2008-2009: I Am Building Healthy Communities," at 12.
[307] *See* Email from R. Joseph Burby, IV, Bryan Cave LLP, to Panel staff (June 7, 2016).
[308] *See* Email from Panel staff to R. Joseph Burby, IV, Bryan Cave LLP (June 7, 2016, 5:09 p.m.); Email from R. Joseph Burby, IV, Bryan Cave, LLP, to Panel staff (June 7, 2016, 5:44 p.m).

not the $380 he had earlier represented.[309] In his email, DVB counsel acknowledged "these records are outside the scope of the Committee's [sic] subpoena, but our client has nevertheless elected to voluntarily provide them to you."[310] On August 10, 2016, DVB's vice president for operations sent a letter to Panel staff changing the amount that DVB, its officers, directors, and employees donated to PPOSBC from $3,030 to $3,620.[311]

On October 11, 2016, the Orange County, California District Attorney filed a lawsuit against DaVinci, DVB, and their corporate officers that alleged the entities violated 42 § 289g-2, and Section 125320 of the California Health and Safety Code that likewise bars the sale of fetal tissue for valuable consideration.[312] The lawsuit alleged that DaVinci and DVB "obtained aborted fetus donations from Planned Parenthood [Orange and San Bernardino Counties] and turned those donations into a profit-driven business," through which the companies wound up "earning hundreds of thousands of dollars in revenue."[313]

8. Business Model of DaVinci and DVB

a) Marketing Activities

DVB began commercial operations in May 2009, without a market strategy. A few months later, the firm launched its first marketing campaign,[314] which stated:

> The marketing challenge for [2009-2010] will be to introduce our products in a politically conscious way given that the material is both human and in some cases pre-natal derived . . . . The challenge will be to form a sales tactic team, infiltrate markets . . . to change existing buyer's outlook and purchasing behaviors . . . [and to make] human cell-derived products well understood and appear worthy of any additional cost to purchase."[315]

Both DaVinci and DVB hired an outside marketing consultant to develop marketing materials, including a catalog, to support their sales effort. The 2010 catalog was posted on the company's website and was sent to various sales leads in an effort to drive sales. The catalogue advertised numerous fetal tissue "products," as part of DVB's LIFEbank brand. The fetal tissues and cells that were listed for sale on the first catalogue included heart, brain, lungs, kidneys, liver, large, intestines, small intestines, skin, skeletal muscle, and bones.[316]

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[309] *See* Email from Joseph R. Burby, IV, Bryan Cave LLP, to Panel staff (June 9, 2016).
[310] *See* Email from Joseph R. Burby, IV, Bryan Cave, to Panel staff (June 9, 2016).
[311] *See* Letter from [DVB Vice President of Operations] to Panel staff (Aug. 10, 2016).
[312] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[313] *Id.*.
[314] *Id.*
[315] *Id.*
[316] *Id.*

The first online catalogue advertised prices in a range as low as $40/vial for Total RNA cells from several fetal parts to as high as $1,100/vial for fetal brain cells. Most products were priced somewhere in the middle of this range ($300-$375/vial for fetal lung cells; $300-$450/vial for fetal kidney cells; $500-$700/vial for fetal heart cells; and $250-$700/vial for fetal liver cells).[317] The current DVB online catalog allows researchers to select from among 338 different types of cells and add the desired product to their "cart."[318] As with the original catalogue, the prices vary dramatically.[319]

DVB's current website catalogue states that customers can "[O]rder anytime, 24 hours a day, 365 days a year by email or fax. If your order arrives outside our normal business hours, it will be quickly processed at the beginning of the next business day."[320] All orders to North America "are shipped from DV Biologics headquarters in Southern California and freight is pre-paid and added to your invoice as a separate item unless customers references their own separate shipping account and vendor."[321] International orders are shipped from DV Biologics headquarters in Southern California every Monday unless specially requested to be shipped on another date.[322]

In late 2011, DaVinci and DVB created a business and marketing plan for the next three years. The plan laid out DaVinci and DVB's three-year goals: "to infiltrate the cell-based market, be a major competitor in the cell-based therapies and tools market for improving health and quality of life, and provide a healthy and conservative balance sheet."[323] The plan's "objective" was to develop the "business units" of DaVinci and DVB "into revenue and value generating subsidiaries."[324] To achieve that, the plan called for "hiring a commercial representative" or "a dedicated sales/marketing person," increasing "the amount of marketing" and the "number of distributors throughout the world and tak[ing] advantage of the internet, distributors, newsletters, educational presentations, and direct marketing/sales."[325]

The plan also called for "penetrating the local American market" by securing a United States distributorship agreement.[326] The business and marketing plan required DVB to "market no less than 10 new products yearly."[327] The driving force behind the business and marketing plan was "to increase sales yearly by no less than 30% each year for the next 3 years . . ."[328]

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[317] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[318] DV Biologics, LLC, LIFEbank Products, http://www.dvbiologics.com/products, Exhibit 5.30.
[319] *Id.*
[320] DV Biologics, LLC, Website, http://www.dvbiologics.com/ordering-information, Exhibit 5.31.
[321] *Id.*
[322] *Id.*
[323] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[324] *Id.*
[325] *Id.*
[326] *Id.*
[327] *Id.*
[328] *Id.*

After a regional sales manager was hired in early 2013, DaVinci and DVB started a 2013 Sales Launch Plan to further increase sales. "The primary objective of [the] plan" was to "help" DVB "meet or exceed its bottom-line goals & objectives," including a goal to "[g]enerate $550,000 in gross revenue by the end of 2013."[329]

The 2013 sales plan also called for improved "selling techniques," the retention of two additional sales managers, and a focus on the sales of "the hottest selling products," which included, among others, the firms' fetal tissue cell lines. In addition, the sales plan expected that the "sales team will go 'above & beyond' what is generally expected," by "heavy prospecting" to generate "leads" and secure sales.[330]

The Orange County District Attorney alleged that, starting in 2012 and for years after under updated marketing and sales plans, both DaVinci and DVB management consistently pushed staff to sell more "product."[331]

As part of its marketing and sales efforts, DVB offered customer discounts.[332] The Orange County District Attorney lawsuit noted DaVinci and DVB "offered numerous discounts, including distributor discounts (20-30%); first time buyer discounts (10-15%); and bulk purchase discounts (sometimes as high as 50%). The company also regularly offered 'sales' pricing promotions, including, for example, a '25% off' summer sale' and '25% off' fall promotion in 2013.[333]

Documents DVB produced to the Panel demonstrate that the District Attorney was correct: Customers who sought a discount had to submit a credit application, that included business references.[334] A DVB operations assistant then contacted the business references and asked them how long the customer has been doing business with the reference, what was their credit line, and whether they always paid on time.[335] If the customer or distributor had three favorable references, they received up a $5,000 maximum credit line upon approval of DVB's vice president for operations. The vice presidents of operations and sales could provide larger unspecified credit lines.[336] If a customer who received a discount paid within 10 days of the invoice date, they could receive an additional early payment discount of 1.5%.[337]

In addition, a tradeshow ad produced by DVB to the Panel shows that attendees of the University of California Riverside Biotechnology Vendor Showcase received a 20% discount

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[329] *Id.*
[330] *Id.*
[331] *Id.*
[332] DV Biologics, LLC, Guidelines for Payments and Discounts, (Feb. 12, 2015) [DVB_00000014–00000018], Exhibit 5.32.
[333] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[334] DV Biologics, LLC, Guidelines for Payments and Discounts, (Feb. 12, 2015) [DVB_00000014–00000018], Exhibit 5.32.
[335] *Id.*
[336] *Id.*
[337] *Id.*

"off their first order! [sic]"[338] DVB also offered customers 10% of their next order if they referred a colleague to DVB.[339] Invoices produced by DVB to the Panel show the firm also offered, in several instances, discounts of 50%, significant "special discounts," complimentary evaluation samples, lower prices for distributors, a 25% holiday discount, and a 15% discount off first orders.[340]

b) DaVinci and DVB's Relationship with Planned Parenthood of Orange and San Bernardino Counties

Both entities received aborted fetal tissue from the same source: Counsel for DaVinci and DVB told the Panel, "DVB received fetal tissue exclusively from its parent company, DaVinci. DaVinci itself received fetal tissue exclusively from Planned Parenthood of Orange and San Bernardino Counties [PPOSBC]." DaVinci claimed it did not pay any money to Planned Parenthood for the donated tissue."[341]

Planned Parenthood Federation of America ("PPFA) told investigators from the Energy and Commerce Committee that PPOSBC "entered into an agreement [with DVB] in September 2008 to facilitate fetal tissue donation by its patients. The affiliate last facilitated tissue donation on June 5, 2015. The program was suspended because [DVB]'s laboratory was undergoing renovations."[342] PPFA also revealed to an earlier investigation that PPOSBC was the only Planned Parenthood affiliate that "has facilitated tissue donation directly to a biosciences company."[343]

A September 23, 2008, contractual agreement between DVB and PPOSBC shows that the firm provided PPOSBC "with a sterile container, including storage media, for each" fetal tissue specimen the Planned Parenthood affiliate obtained.[344] On each day DVB was scheduled to obtain fetal tissue, PPOSBC workers would, "following retrieval, store each [fetal tissue] Specimen in a separate container" and notify DVB's "designated contact . . . that Specimen is ready for pick-up . . . ."[345]

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[338] DV Biologics, LLC, Biotechnology Tradeshow Ad, undated [DVB_00000289], Exhibit 5.33.
[339] DV Biologics, LLC, Customer Referral Program, Sept. 5, 2014, at 6 [DVB_00000254], Exhibit 5.34.
[340] *See* Invoices produced to the Panel by DaVinci Biologics, LLC (May 27, 2016).
[341] *See* Letter from Joseph R. Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel 3 (Jan. 29, 2016).
[342] Planned Parenthood Federation of America, "Follow-up Questions Dated August 20, 2015: U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations," at 2 [PPFA-HOU_E&C-0000162 – PPFA-HOU_E&C-000169], Exhibit 5.35.
[343] Planned Parenthood Federation of America, "Follow-up Questions Dated August 20, 2015: U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations" [PPFA-HOU_E&C-0000259 – PPFA-HOU_E&C-000262], Exhibit 5.36.
[344] Specimen Donation Agreement between DaVinci Biosciences, LLC, and Planned Parenthood of Orange and San Bernardino Counties (Sept. 23, 2008) [DVB_00001613 – DVB00001622], Exhibit 5.37.
[345] Planned Parenthood Federation of America, "Follow-up Questions Dated August 20, 2015: U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations" [PPFA-HOU_E&C-0000259 – PPFA-HOU_E&C-000262], Exhibit 5.36.

The 2008-2009 program report of PPOSBC listed DaVinci as having donated between $1,000 and $2,499 to the Planned Parenthood affiliate.[346] DVB's contract with PPOSBC is dated September 23, 2008.[347] Documents produced by DVB to the Panel show officials with the firm donated $2,190 to PPOSBC during 2008 alone, including four separate $500 "charitable donation[s]" on April 24, 2008.[348] That date is significant because it not only predates by nearly five months DVB's contract with PPOSBC, but also because invoices produced by DVB to the Panel show that less than one year later, on April 1, 2009, the firm first transferred human fetal tissue to a customer.[349] In 2009, DVB donated another $500 to PPBOSBC.[350]

DVB's attorney represented that "the individuals responsible for these donations have not worked at DV Biologics since approximately 2011. The company underwent a significant change in management at that time."[351] [DVB Executive #1], who contributed $2,500 to PPOSBC before the PPOSBC contract was signed, was named by the Orange County District Attorney as DaVinci's manager and chief executive officer.[352] However, in 2012, DVB donated $380 more in two separate $190 donations to PPBOSCB.[353] It is unclear why DVB made the two donations if the individuals responsible for the earlier donations had left, along with key management officials.

Documents produced by other firms in the fetal tissue industry to the Panel pursuant to subpoenas demonstrate that the industry norm is for companies, both for-profit or non-profit, to pay California-based abortion clinics for fetal tissue. For example, StemExpress, LLC, another for-profit tissue procurement firm, paid Planned Parenthood affiliates in California an average of $50 per-specimen obtained.[354] Advanced Bioscience Resources, Inc., a non-profit tissue procurement business, paid facility fees of $55 or $60 per month (depending upon the year) to the Planned Parenthood affiliates and clinics from which it obtained fetal tissue.[355] From 2010 through 2015, StemExpress paid a total of $135,880 to California-based Planned Parenthood affiliates for fetal tissue specimens.[356] Over the same time period, Advanced Biosciences

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[346] See Planned Parenthood of Orange and San Bernardino Counties, "Program Report 2008-2009: I Am Building Healthy Communities," 12.
[347] Specimen Donation Agreement between DaVinci Biosciences, LLC, and Planned Parenthood of Orange and San Bernardino Counties (Sept. 23, 2008) [DVB_00001613–DVB00001622], Exhibit 5.37.
[348] DV Biologics, LLC, "Transactions Detail by Account, January 1, 2007 through September 28, 2015."
[349] DV Biologics, LLC, Invoice Number 1, Apr. 1, 2009.
[350] DV Biologics, LLC, "Transactions Detail by Account, January 1, 2007 through September 28, 2015."
[351] Email from R. Joseph Bury, IV, Bryan Cave LLP, to Panel staff, June 9, 2016.
[352] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[353] DV Biologics, LLC, "Transactions Detail by Account, January 1, 2007 through September 29, 2015."
[354] *See* Services Agreement between StemExpress, LLC, and Planned Parenthood Mar Monte, Apr. 1, 2010, at 1 [STEM_HOUSE.SELECT_0167–STEM_HOUSE.SELECT_0169]; Services Agreement between StemExpress, LLC, and Planned Parenthood Shasta Pacific (May 15, 2012) 1 [STEM.HOUSE.SELECT_0170–STEM.HOUSE.SELECT_0172]; Services Agreement between StemExpress, LLC, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties 1 (Oct, 23, 2013).
[355] Advanced Bioscience Resources, Inc., "Statement of Facility Fees, Jan. 2010 – Oct. 2015."
[356] Panel analysis of invoices from Planned Parenthood Mar Monte and Planned Parenthood Shasta Pacific to Stem Express, LLC.

Resources, Inc. paid a total of $328,225 to California-based Planned Parenthood affiliates for fetal tissue specimens.[357]

c) Revenue Growth

When DVB began its commercial operations in May 2009, the company had "minimal product inventory and no marketing or sales."[358] Between 2009 and 2011, sales revenues nearly tripled.[359] By 2012, DaVinci and DVB's products were "valued at much greater than $4.4 million."[360] An undated audit of DaVinci and DVB stated the value of the firms' inventory could be as high as $10 million.[361]

The Orange County District Attorney alleged that DVB's goal in 2013 was to generate $555,000 in revenue by the end of the year.[362] Those goals were slightly high: In both 2013 and 2014, the company grossed in excess of $400,000 in revenue—double that of 2012. In 2015, the firms continued their upward momentum and exceeded $550,000 in gross revenues.[363] The District Attorney alleged, "When subtracting the cost of goods sold, DV produced a gross profit on sales every year, except 2012."[364]

9. Consent & Procurement During the Abortion Procedure

Documents produced by DVB to the Panel show that PPOSCB workers performed the following tasks:

- Discussed tissue donation with women awaiting abortions;
- Obtained consent from the patients to donate human fetal tissue;
- Procured fetal tissue of between a gestational period of 5-20 weeks;
- Stored the signed consent forms;
- Collected the fetal tissue samples, washed the samples, and transferred them to a sterile container with the gestational age written on the container; and,

[357] Panel analysis of invoices from Planned Parenthood San Jose, Planned Parenthood Riverside, and Planned Parenthood to Advanced Bioscience Resources, Inc.
[358] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[359] *Id.*
[360] *Id.*
[361] *Id.*
[362] *Id.*
[363] *Id.*
[364] *Id.*

- Stored the samples on wet ice, which were transported by DVB employee(s).[365]

10. Post-Procedure Practices

DV employees received the fetal tissue, noting the harvest date, the pickup time, the arrival time, the organ/tissue, gender, which employee picked up the tissue, whether the tissue was discarded, and if so, why.[366] Once the tissue was logged in, DVB employees then processed the fetal tissue, checked it in, "[i]dentified fetal organs" "mechanically minced and enzymatically digested" the organs, cultured the isolated cells, and, in some instances "cryopreserved" the cells or cell lines at DVB.[367]

11. Customers that Received Fetal Tissue from DaVinci and DVB

DaVinci and DVB sold the fetal tissue to researchers, educational institutions, and pharmaceutical companies. DaVinci "focused on the research and development of cell-based therapeutics targeting neurodegenerative and autoimmune diseases, while DVB supplied human biological tools to academic institutions and pharmaceutical companies for research purposes."[368]

Roughly half of all DVB's customers were foreign entities.[369] DVB's domestic customers were, in chronological order:

- The University of Utah Cell Therapy Facility
- VA Health Center - Long Beach
- University of Connecticut Health Center
- Cedars-Sinai Medical Center
- University of Texas San Antonio
- University of California Irvine Department of Radiation
- Life Technologies
- Cleveland Clinic

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[365] DaVinci Biosciences, LLC, Characterization of Human Fetal Stem Cells and Determination of Research and Therapeutic Tool Potential, undated [DVB_00001611-0000612], Exhibit 5.38.
[366] DaVinci Biosciences, LLC, Form 101, Prenatal Receiving, undated [DVB_00000062], Exhibit 5.39.
[367] DaVinci Biosciences, LLC, Characterization of Human Fetal Stem Cells and Determination of Research and Therapeutic Tool Potential, undated [DVB_00001611-0000612], Exhibit 5.38.
[368] *See* Letter from R. Joseph Burby, IV, Bryan Cave LLP, to Rep. Marsha Blackburn, Chair, Select Investigative Panel (Jan. 29, 2016).
[369] Panel analysis of invoices produced by DaVinci Biologics, LLC.

- City of Hope
- Cellular Dynamics International
- SA Biosciences Corporation
- StemCell Technologies, Inc.
- Omeros Corporation
- University of Wisconsin Medical College
- University California Merced
- Procter & Gamble (Miami Valley Innovation)
- Stanford University
- Fisher Scientific
- UNIVSION USA
- B-Bridge International Inc.
- iPierian, Inc.
- AgenSys
- Aloecorp, Inc.
- Santa Cruz Biotechnology, Inc.
- Zyagen
- Trim-edcine
- WuXi App Tech, Inc.
- Tufts University
- Royspec
- J. David Gladstone Institutes

- Applied StemCell, Inc.
- Gentech
- Creative Biolabs, Inc.
- Baylor College of Medicine
- RaNa Therapeutics, Inc.
- MatTek Corporation
- New York Medical Center
- Tufts University Department of Biomedical Research
- University of Washington
- Organovo
- Amira Pharmaceuticals Inc.
- New York University Langone Center
- University of Texas Medical Branch
- National Institutes of Health
- Brigham & Women's Hospital
- Abbvie, Inc.
- Quorum Innovations
- Earth Science Tech.[370]

[370] Invoices produced by DaVinci Biologics, LLC, to the Panel.

12. Potential Violations of Law

c) Applicable Laws

l) 42 U.S.C. § 289g-2

The applicable federal law on fetal tissue is 42 U.S.C. § 289g-2(a), which states "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Under that law, "The term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[371] Human fetal tissue is defined broadly to include any "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth."[372]

ii) California Health and Safety Code Section 125320

The California Health and Safety Code contains virtually identical language as 42 U.S.C. § 289g-2. That law states that:

> (d) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.
>
> (e) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.
>
> (f) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.[373]

As with 42 U.S.C. § 289g-l(g), another provision of the California Health and Safety Code also broadly defines tissue to "mean a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body . . . ."[374]

iii) California Revenue and Tax Code

A provision of the California Revenue and Tax Code states that:

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[371] 42 U.S.C. § 289g-2(e)(3)
[372] 42 U.S.C. § 289g-l(g).
[373] Cal. Health & Safety Code § 125320.
[374] Cal. Health & Safety Code § 1635(c).

> [E]very retailer engaged in business in this state and making sales of tangible personal property for storage, use, or other consumption in this state, not exempted . . . shall, at the time of making the sales or, if the storage, use, or other consumption of the tangible personal property is not then taxable hereunder, at the time the storage, use, or other consumption becomes taxable, collect the tax from the purchaser and give to the purchaser a receipt therefor in the manner and form prescribed by the [California State Equalization Board].[375]

The law defines a "retailer engaged in business in" California as "Any retailer maintaining, occupying, or using, permanently or temporarily, directly or indirectly, or through a subsidiary, or agent, by whatever name called, an office, place of distribution, sales or sample room or place, warehouse or storage place, or other place of business."[376]

There is an exemption for the sale of human blood and human body parts.[377] DVB is not a tissue or blood bank. Rather it sells fetal tissue cells, cell lines, and other products directly to customers. The California State Board of Equalization ("SBE") recently collected nearly $82,000 for unpaid sales taxes for a non-profit organization that saves dogs, draws blood from those dogs, and sells the white blood cells, plasma, and red blood cells for transfusions into other canines.[378]

The statute defines tangible personal property as "personal property which may be seen, weighed, measured, felt, or touched, or which is in any other manner perceptible to the senses."[379] Thus, cells and cell lines are tangible personal property under the California Sales and Use Tax.

An SBE publication states that California companies can pass along the amount of sales tax to customers, provided the business lists a separate amount for sales tax reimbursement on its receipts or invoices, or if the sales agreement "specifically calls for the addition of sales tax reimbursement."[380] If the business includes sales tax reimbursement in its prices, companies "must inform the buyer that tax is included" by making one of the following statements on a price tag or in an advertisement: "All prices of taxable items include sales tax reimbursement computed to the nearest mill," or "The price of this item includes sales tax reimbursement to the

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[375]Cal. Rev. & Tax Code § 6203. A publication put out by the State Board of Equalization ("SBE") states that provision applies to corporations, individuals, Limited Liability Companies, Limited Liability Partnerships, Limited Partnerships, partnerships, married co-owners, registered domestic partnerships, and organizations. Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 1.

[376] Cal. State Bd. of Equalization, "Laws, Regulations & Annotations, Sales and Use Tax Law, Chapter 3. The Tax." https://www.boe.ca.gov/lawguides/business/current/btlg/vol1/sutl/6203.html.

[377] Cal. Rev. & Tax Code § 33 ("Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.").

[378] Chris Haire, "Greyhound Dog Rescue Hemopet Fights to Stay Open after $82,000 Tax Bill," *Orange County Register*, Oct. 10, 2016, http://www.ocregister.com/articles/blood-731674-hemopet-greyhounds.html.

[379] Cal. Rev. & Tax Code § 6016.

[380] Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 5.

nearest mill."[381] Neither of those statements are on DVB's website or in the advertisement produced to the Panel by DVB.[382]

Under the California Revenue and Tax Code,

> Internet sales are treated just like sales made at retail stores, by sales representatives, over the telephone, or by mail order. If your business is located in California, retail sales of tangible personal property that you make over the Internet to California customers are generally taxable unless the sales qualify for a specific tax exemption or exclusion . . . and you are required to register for a permit and report and pay tax to the same extent as any other retailer in California.[383]

d) Findings

j) 42 U.S.C. § 289g-2 & California Health and Safety Code Section 125320

The Orange County District Attorney alleged that DaVinci and DVB's costs to process fetal tissue were minimal: a limited number of labor hours (2-9 hours per product) and that it cost the firms an average of less than $20/vial.[384]

Internal company documents cited in the District Attorney's lawsuit show that DaVinci and DVB sold fetal tissue for valuable consideration. Human Cardiomyocytes cells derived from fetal tissue were produced at a cost including labor of $25.92 per vial; DaVinci and DVB sold it for between $350-per vial and $700-per vial, which amounted to between $324.08 and $674.08 in profit for each vial sold (not including any profits earned on packaging and handling or other fees).[385]

Human Cardiac Progenitor cells, also derived from fetal tissue, were produced at a total cost of $62.31 per vial; the product sold for between $455 and $650-per vial, which amounted to between $392.69 and $587.69 profit for each vial.[386] Another product derived from fetal tissue, Human Whole Liver Cells cost $18.46 per vial to produce; the vials sold for between $125 and $200 a vial, which meant the companies made profits of between $106.54 and $181.54 for each vial.[387] Human CD34 Positive Cells, also derived from fetal liver tissue donations, cost $126.17

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[381] *See* Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014.
[382] DVB Advertisement, Exhibit 5.33.
[383] Cal. State Bd. of Equalization, "Publication 109 Internet Sales," https://www.boe.ca.gov/formspubs/pub109/.
[384] Complaint, People v. DV Biologics, LLC, et al., 201600880665, (Cal. Super. Ct., Orange County, Oct. 11, 2016), Exhibit 5.28.
[385] *Id.*
[386] *Id.*
[387] *Id.*

per vial to produce; it sold for between $225 and $360 for each vial—a profit of between $98.83 and $233.83 per vial.[388]

Stomach cells, also derived from fetal tissue, sold for between $210 and $240 per vial. It cost DaVinci and DVB $18.46 to produce ten vials. Thus, the firms earned a profit of between $191.54 and $221.54 per vial.[389] Two other products that came from fetal tissue, Human Small Intestine Cells (uncultured) and Human Large Intestine Cells were produced in ten-vial lots at a total cost of $18.46 per vial—a profit of between $191.54 and $281.54 per vial.[390] Another product derived from fetal tissue, Human Small Intestine Epithelial Cells, were manufactured in 10 vials at a cost of $35.91 per vial; DaVinci and DVB sold it for between $297.50 and $700 a vial, which amounted to a per-vial profit of between $261.59 and $664.09.[391]

ii) California Revenue and Tax Code

As previously noted, DVB sold its products through the Internet. It should, therefore, have collected tax on sales made to California customers. Seventeen invoices produced by DVB show the firm did not charge tax to California-based clients.[392] The invoices are listed in the chart below:

CUSTOMER	DATE	INVOICE NUMBER	AMOUNT OF SALE	SALES TAX CHARGED
Life Technologies	Feb. 9, 2010	017	$1,500	0
Life Technologies	Jun. 29, 2010	042	$2,425	0
Life Technologies	Jun. 29, 2010	043	$2,390	0
Life Technologies	Aug. 3, 2010	053	$ 631	0
Life Technologies	Sep. 7, 2010	064	$2,415	0

[388] *Id.*
[389] *Id.*
[390] *Id.*
[391] *Id.*
[392] Invoices from DV Biologics, LLC, to Life Technologies, Exhibit 5.40.

Life Technologies	Oct. 6, 2010	073	$1,078	0
Applied StemCell, Inc.	Oct. 31, 2012	387	$ 450	0
Applied StemCell, Inc.	May 16, 2013	504	$1,214	0
Applied StemCell, Inc.	Jun. 4, 2013	517	$ 152.99	0
Applied StemCell, Inc.	Sep. 9, 2013	600	$ 82	0
Applied StemCell, Inc.	Oct. 1, 2013	618	$ 450	0
Applied StemCell, Inc.	Oct. 7, 2013	622	$1,570	0
Applied StemCell, Inc.	Mar. 6, 2014	754	$4,016.99	0
Applied StemCell, Inc.	Jun. 30, 2014	837	$ 218	0
Applied StemCell, Inc.	Aug. 13, 2014	869	$ 592.99	0
Applied StemCell, Inc.	Aug. 18, 2014	871	$ 856.99	0
Applied StemCell, Inc.	Feb. 24, 2015	1077	$1,250	0

13. Conclusion

The Panel referred DVB's potential violations of the California Revenue and Tax Code to the Orange County District Attorney. The Panel referred DVB's potential violation of Title U.S.C. § 289g-2 to the United States Department of Justice.

C. Novogenix Laboratories, LLC: A Case Study

10. Summary

The Panel has uncovered evidence that Novogenix Laboratories, LLC (Novogenix) may have violated laws, including 42 §289g-2, Cal. Health & Safety Code § 125320(a), provisions of the California Tax Revenue and Tax Code, and regulations promulgated by the U.S. Department of Health and Human Services.

a) Background of Novogenix

Novogenix was founded as a for-profit corporation with the California Secretary of State on February 24, 2010, by [Founder and Executive Director].[393] As of October 2015, Novogenix went out of business.[394] Documents produced by the U.S. Food and Drug Administration (FDA) to the Panel show that Novogenix may not have registered with the FDA.[395] Novogenix claimed its work with fetal tissue and stem cells derived from fetal tissue "was exclusively for the purposes of scientific research, and was not used for therapeutic or transplantation purposes."[396] If true, Novogenix was not regulated by the FDA. [Founder and Executive Director], owner of the company told the investigators from the Committee on Energy and Commerce inquiry into the fetal industry that, during the time Novogenix was operating 70%-80% of its business was selling services related to fetal tissue.[397] Those services included the procurement of fetal tissue, the creation of stem cells from fetal tissue, and the shipment of those fetal tissues and stem cells to scientists engaged in research.[398]

b) History of the Panel's Interactions with Novogenix

On December 17, 2015, the Panel sent Novogenix a document request letter requesting a list of all entities from which it procured fetal tissue, a list of all entities to which it sold or donated fetal tissue, an organization chart, all communications that direct its employees to procure fetal tissue, accounting records, and all Novogenix banking records related to the procurement, sale, donation, or distribution or shipment of fetal tissue.[399]

Citing its productions to preliminary congressional investigations into the fetal tissue industry, and that the firm had stopped doing business, Novogenix initially refused to provide

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[393] California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov.

[394] *See* Letter from Joshua A. Levy, Cunningham Levy LLP, to Rep. Fred Upton, Chairman, Committee on Energy and Commerce 1 (Oct. 6, 2015); Letter from Joshua A. Levy, Cunningham Levy LLP, to Panel staff (Dec. 22, 2015); California Secretary of State, Business Entity Detail, http://kepler.sos.ca.gov.

[395] Email from [Supervisor Consumer Safety Officer], U.S. Food and Drug Administration, to [Consumer Safety Officer], U.S. Food and Drug Administration (Sept. 14, 2014).

[396] *See* Letter from Joshua A. Levy, Cunningham Levy LLP, to Charles Ingbertson, Chief Counsel, Committee on Energy and Commerce 2 (Sept. 2, 2015), Exhibit 5.4.1.

[397] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42

[398] *Id.*

[399] *See* Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [Founder and Executive Director] Novogenix Laboratories, LLC (Dec. 17, 2015), Exhibit 5.4.2

any responsive documents.[400] Novogenix refused to provide the names of the research institutions to whom it supplied fetal tissue "not only out of consideration for the well being [sic] of the people working at these entities, but also out of respect for [Novogenix's] non-disclosure agreements" with its customers.[401] Novogenix said it was "working with dispatch to reach out to" its former customers "in order to determine whether any of them would consent to our disclosure of their names to the Select Panel."[402] Over the next month, Novogenix produced to the Panel the names of some of its customers.[403]

After Novogenix provided only some customers names, on April 29, 2016, the Panel authorized a subpoena that required production of the documents first requested in the December 17, 2015, letter, including the communications with its employees, accounting documents, and all banking records.[404] Following a telephone conference with Novogenix counsel, the Panel agreed not to serve the subpoena, if Novogenix provided the names of all its former customers by May 31, 2016.[405] Novogenix produced the names of entities that "have received over 99% of the fetal tissue that Novogenix has donated."[406]

To date, the Panel has not received any communications that relate to fetal tissue, as well as any accounting or banking records. Senior law enforcement attorneys and other witnesses who testified at the Panel's April 20, 2016, hearing, "The Pricing of Fetal Tissue," stated accounting and banking documents were critical to any analysis of § 289g-2.[407]

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[400] *See* Letter from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff 1 (Dec. 22, 2015), Exhibit 5.4.3.
[401] *See* Letter from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff 1 (Feb. 16, 2016), Exhibit 5.4.4.
[402] *Id.*
[403] *See* Letter from Joshua A. Levy, Cunningham Levy Muse, LLP, to Panel staff, Feb. 24, 2015; Letter from Joshua A. Levy, Cunningham Levy Muse, LLP, to Panel staff (Feb. 26, 2015); Letter from Joshua A. Levy, Cunningham Levy Muse, LLP, to Panel staff (Mar. 2, 2015); Letter from Joshua A. Levy, Cunningham Levy Muse, LLP, to Panel staff (Mar. 21, 2015).
[404] Subpoena to Novogenix Laboratories, LLP, (April 29, 2016), Exhibit 5.4.5.
[405] Telephone conference between Joshua A. Levy, Cunningham Levy Muse LLP, and Panel staff (May 3, 2016); Email from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff (May 6, 2016); Email from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff (May 19, 2016).
[406] *See* Letter from Joshua A. Levy, Cunningham Levy Muse LLP, to March Bell, Staff Director and Chief Counsel, Select Investigative Panel 2 (May 31, 2016), Exhibit 5.4.6.
[407] *The Pricing of Fetal Tissue: Hearing before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, 114th Cong. (Apr. 20, 2016). In particular, the witnesses made the following statements when asked by Chairman Blackburn what information the Panel should pursue:

> Former Senior Litigation Counsel, U.S. Department of Justice - Brian Lennon: The only element where investigation is needed, and that would include I believe forensic accounting and analysis thereof, is whether the payments made by the research institutions that ultimately receive the human tissue to the procurement businesses were a valuable consideration or, alternatively, reasonable payments associated with the specific allowable services in the statute... Because the businesses do in fact incur costs associated with these delineated services, a forensic accounting would be essential to breaking down the company's financials. *Pricing of Fetal Tissue*, unedited transcript, at 53.
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> Former United States Attorney- Kenneth Sukhia: I would also want to know what communications occurred between—other communications, email and so forth,
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11. Novogenix Business Model

a) Marketing Activities

[Founder and Executive Director] stated that Novogenix had no formal marketing plan. Rather, researchers reached out to Novogenix for fetal tissue needs directly to [Founder and Executive Director], because of his reputation in the field of stem cell research.[408]

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back and forth between those people. We would seek those items as well, and of course the accounting records. *Pricing of Fetal Tissue*, unedited transcript, at 79.

Former United States Attorney Mike Norton: First of all, I would start by looking at the videos, which I have seen. I would start by reading the forensic accounting report by Coalfire Investigations made up of former FBI agents, which found that the videos were credible and the redacted versions say what the longer versions say. I would obtain the accounting records, the financial records of the abortion clinic, of the procurement business, and, frankly, I would obtain the records of the end user as well, and subpoena both records and witnesses from all of those entities to flesh out the facts in this case, which I think are there. *Pricing of Fetal Tissue*, unedited transcript, at 125-26.

Brian Lennon: As I said in my opening, you need a forensic—if I was a prosecutor, you have to have a forensic evaluation accounting of the procurement business, because that is not clear from the records here. So following the money, you have got to have the entire picture. *Pricing of Fetal Tissue*, unedited transcript, at 139.

Mike Norton: I would get forensic accounting. I would get all of the financial records. I would get the profit and loss statements, the income and expense statements, and I would get people under oath before a grand jury. Letters are not particularly valuable. *Pricing of Fetal Tissue*, unedited transcript, at 139.

Attorney Catherine Glenn Foster: There are two things that I would specifically seek among many different documents. First of all, financial records. That is something that must be brought to light. And, second, women of every generation are unique human beings who can speak for themselves, but the baby body parts profiteers have created a market in which their profits rise if they pressure and coerce women into signing donation consent forms. *Pricing of Fetal Tissue*, unedited transcript, at 140.

Attorney Fay Clayton: The second thing I would do is ask them, in each particular case, what aspect of the actual costs does a particular clinic incur? For example, does the clinic provide space? Does the clinic, as we have seen in your charts, provide the blood draws which requires a technician, perhaps a nurse, materials? Does the clinic have to do paperwork? And, if so, how much? And, therefore, how much of the actual reasonable cost is incurred by the clinic itself as opposed to by the procurement business? *Pricing of Fetal Tissue*, unedited transcript, at 138.

[408] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.

b) Novogenix's Relationship with Abortion Clinics

Novogenix had a contract to procure fetal tissue from Planned Parenthood Los Angeles (PPLA). The contract provided that Novogenix would "reimburse PPLA for reasonable administrative costs associated with the identification of potential donors, as well as the obtaining of informed consent. This amount will be $45 per donated specimen."[409] Novogenix's relationship with PPLA ended in 2015 as a direct result of the Center for Medical Progress' videos and resulting press reports.[410]

[Founder and Executive Director] stated that Novogenix obtained tissue from other unnamed clinics "on an ad hoc basis," but Novogenix had no contracts or written documents with those clinics, "just informal agreements."[411]

c) Revenue Growth

Novogenix counsel told the panel, "Novogenix has not sold fetal tissue. Rather, Novogenix contracted with a number of scientists to be reimbursed for the costs of services performed by Novogenix . . . ."[412] [Founder and Executive Director] acknowledged that his understanding of which costs are reimbursable was based on his legal understanding that Novogenix sold services, not fetal tissue.[413] When he was pressed on that point, [Founder and Executive Director] would not answer, citing attorney-client privilege.[414]

The company initially set its prices at $200 for each service performed, however those prices increased each year.[415] [Founder and Executive Director] calculated that figure by adding $50 related to reagents, and $150 based on his projection of fixed costs.[416] [Founder and Executive Director] said he did not calculate how many services Novogenix would perform, how many researchers would obtain his firm's products, or the service volume.[417] He explained that the costs increased each year.[418] [Founder and Executive Director]'s goal was for Novogenix to break even over time.[419]

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[409] Specimen Donation Agreement between Novogenix Laboratories, LLC, and Planned Parenthood Los Angeles (Mar. 1, 2010), Exhibit 5.41.
[410] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42; Planned Parenthood Federation of America, Response to Follow-Up Questions from the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations (Aug. 20, 2016).
[411] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.
[412] Letter from Joshua A. Levy, Cunningham Levy Muse LLP, to Panel staff 1 (Dec. 22, 2015), Exhibit 5.4.3; 5.4.4.
[413] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), [Founder and Exeeutive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.
[414] *Id.*
[415] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce, Sept. 3, 2015.
[416] *Id.*
[417] *Id.*
[418] *Id.*
[419] *Id.*

Invoices produced to the Panel by some of Novogenix' customers show that it received a total of $170,980.59 from 7 research institutions between June 2011 and December 2015.[420] The Panel cannot determine either the total number of Novogenix' customers or its revenue.

The firm's counsel represented that it lost a total of $160,540.03 on its fetal tissue operations.[421] Novogenix conceded that its "counsel created [the expenses and revenue document] . . ."[422] The Panel cannot rely on the expenses and revenue document because it was created by counsel, and Novogenix produced no primary source accounting records. Thus, the Panel cannot determine whether Novogenix actually lost money on its fetal tissue operations.

However, the list of expenses included an unknown amount for attorney fees.[423] Such fees are not included under the list of allowable reimbursements under § 289g-2. The list of expenses also included minimal amounts for delivery to researchers.[424] Invoices produced to the Panel by Novogenix customers show the firm charged delivery fees of up to $122.43 per shipment,[425] raising further questions about the reliability of the attorney-created cost document.

12. Consent

PPLA personnel obtained consent from patients to donate tissue from their aborted fetuses.[426] [PP Witness #1] explained that PPLA workers identified fetuses of between 9 and 16 weeks; obtained informed consent for the abortion, and informed women that PPLA had a program for tissue donation, and, if the patient was interested, PPLA workers obtained consent to donate fetal tissue.[427]

PPLA took the standard PPFA consent form,[428] which stated, "Research using . . . tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes,

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[420] Panel analysis of invoices produced by Children's Hospital of Philadelphia; City of Hope; Rockefeller University; Stanford University; the University of Connecticut Health Center; the University of California, Los Angeles; and the University of Southern California.
[421] Novogenix Laboratories, LLC, Expenses and Revenue FY 2011 – FY 2015, undated. [NOVOEC-0000006–NOVOEC-0000014], Exhibit 5.43. Novogenix' fiscal year ran from September through August of the following calendar year.
[422] Letter from Joshua A. Levy, Cunningham Levy LLP, to Charles Ingbertson, Chief Counsel, Committee on Energy and Commerce 2 (Sept. 2, 2015), Exhibit 5.4.1.
[423] Novogenix Laboratories, LLC, Expenses and Revenue FY 2011 – FY 2015, undated. [NOVOEC-0000006–NOVOEC-0000014], Exhibit 5.43.
[424] *Id.*
[425] Panel analysis of invoices produced by Children's Hospital of Philadelphia; City of Hope; Rockefeller University; Stanford University; the University of Connecticut Health Center; the University of California, Los Angeles; and the University of Southern California.
[426] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7
[427] *Id.*
[428] *Id.*

Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[429] There is no cure for those diseases.

Numerous witnesses, including senior PPFA officials, testified that the consent form is misleading and unethical due to its contention that fetal tissue has been used to find a cure for diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS. [PP Witness #1] testified that the PPFA consent form contained inaccurate statements, and that she, the person who oversees the production of the PPFA manual that contains the consent form, was not happy that an inaccurate document was in the manual:

> Q: Have we found a cure for cancer?
> A: If we had found a cure, we wouldn't be asking for tissue donations to try to find a cure.
> Q: Have we found a cure for AIDS?
> A: Not that I'm aware of, not yet.[430]
> [A:] . . . To my knowledge there is no cure for AIDS. So that is probably an inaccurate statement . . . . a consent form should not have an incorrect statement [on it].[431]

When [PP Witness #1] was asked whether it bothered her that an inaccurate consent form was in the PPFA Manual of Medical Standards and Guidelines, she testified: "I guess it bothers me. I mean, I oversee the production of the standards . . . . it doesn't make me happy that there's something inaccurate in the manual."[432]

Regulations promulgated by the U.S. Department of Health and Human Services (HHS) on informed consent states that investigators "shall seek such consent only under circumstances that provide the prospective subject with . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."[433] The regulations further state: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as . . . pregnant women . . . additional safeguards" are included.[434]

[PP Witness #1] testified that the PPFA consent form used by Novogenix may coerce women to donate fetal tissue. When she was asked whether the "incorrect statement" that fetal tissue has found a cure for various diseases "could be viewed as coercive or . . . more likely to induce somebody to want to donate fetal tissue," [PP Witness #1] testified: "I can understand your concern that perhaps this may make someone think about donating fetal tissue because of

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[429] Planned Parenthood Federation of America, PPFA Manual of Medical Standards and Guidelines, Client Information and Informed Consent, Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment," Revised June 2011, Exhibit 5.44.
[430] Unedited transcribed interview of [PP Witness #1] 130 (Oct. 6, 2016).
[431] *Id.* at 131.
[432] *Id.* at 134.
[433] 45 C.F.R. § 46.116.
[434] 45 C.F.R. § 46.111(7)(b).

this potential."[435] She also stated that the PPFA consent form's wording may make patients more likely to want to donate fetal tissue.[436]

Dr. Patrick Lee, a leading bioethicist testified at a Panel hearing that the PPFA form may be coercive and likely is unethical.

> Mr. Harris: . . . I am going to ask Dr. [Patrick] Lee, because you are a bioethicist, is [the PFFA consent] form ethical where you tell a patient that diabetes, Parkinson's disease, Alzheimer's disease, cancer and AIDS, that [fetal] tissue has been used to find a cure? Past tense. It is not that we going to use it to find a cure, it has been used to find a cure. . . . Is that unethical to ask this woman at a time when she is making a difficult decision to say that this tissue has been used to cure diseases when it hasn't?
>
> Mr. [sic] Lee: No, in order to make a fully informed consent, you have to be given accurate information.[437]

13. Procurement

PPLA procured the fetal tissue, as well as obtained consent. The Novogenix contract with PPLA stated that the firm would "provide PPLA with a sterile container, including storage media, for each Specimen."[438] The contract further states:

> On each PPLA operating surgery day during which the retrieval of Specimens is scheduled, PPLA will: (i) identify patients for potential donation; (ii) obtain informed consent from patients who agree to participate in tissue donation programs; (iii) following pathology analysis of donated specimens [conducted by PPLA], allow Novogenix's [sic] designated contact . . . to select material for collection.[439]

[PP Doctor #1] stated that PPLA surgeons would procure the tissue. She stated if women agreed to donate tissue, PPLA workers would flag their charts, so the surgeon would know that she had agreed to donate fetal tissue.[440] [PP Doctor #1] also stated that, if PPLA performed an abortion on a woman who had a 12-week-old fetus, Novogenix would take all or part of the fetus.[441]

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[435] Unedited transcribed interview of [PP Witness #1] 131-132 (Oct. 6, 2016).
[436] *Id.* at 132.
[437] *Bioethics and Fetal Tissue: Hearing before the Select Investigative Panel of the H. Comm. on Energy and Commerce*, Mar. 2, 2016, at 140-141.
[438] Specimen Donation Agreement between Novogenix Laboratories, LLC, and Planned Parenthood Los Angeles (Mar. 1, 2010), Exhibit 5.41.
[439] *Id.*
[440] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[441] *Id.*

[PP Doctor #1] testified that she met with the Novogenix tissue technicians before abortions were performed to determine what type of fetal tissue the firm needed that day, and that such meetings are helpful:

> Q: Now, do you think that doctors in your position should huddle in the morning? You say, "I like to do that." It's sort of an ongoing tense. Do you think the doctors should huddle with a tissue tech to see what they're procuring, is on their list that day?
> A: I don't really have a feeling as to whether other doctors did. I like to be helpful.
> Q: And so you found it helpful that at least on this one day to huddle with the tissue tech and learn what [the Novogenix tissue technician] was searching for, what orders she had; is that right?
> A: I would ask her what tissue she was looking for, yes.
> Q: All right. Do you think that's a good idea for the whole fetal tissue donation program, that doctors and the tissue techs huddle each morning to discuss what they're going to try and procure that day?
> A: I think it could be helpful.[442]

14. Post-Procurement Practices

[PP Doctor #1] stated that, after the abortions were performed and PPLA surgeons procured the fetal tissue, a Novogenix technician would take the tissue to the firm's facility.[443] Novogenix processed the tissue. This generally involved methods to isolate specific cells, generate a single cell suspension from a parent tissue, machine the cell to allow for the simultaneous separation into 4-6 populations of cells based on the protein expression on the surface of the cells.[444]

[Founder and Executive Director] stated that there were two basic post-procurement procedures: In the first, fetal tissue would be collected at the clinics by Novogenix personnel, who would take the specimens back to the laboratory; the firm would freeze the tissue with various chemical fixatives, which preserves the cells; after that step was completed, workers would wash the chemicals out of the material; prepare it for shipping, which included the dissection of the tissues into thin slices; and ship the finished product to the researcher. The second method involved fetal tissue that already had been isolated under the first method. The isolated cells would be stored on-site at Novogenix, double-layered to preserve it, prepared for shipment, and shipped once a researcher requested those particular cells.[445]

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[442] Unedited transcribed interview of [PP Witness #1] 142 (Oct. 6, 2016).
[443] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[444] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.
[445] *Id.*

Because Novogenix did not produce any primary source accounting records, the Panel cannot determine many of the firm's costs. Invoices produced to the Panel by a number of leading research institutions show that Novogenix charged some of its customers for what the firm called services, as well as shipping. Those costs varied. Due to the dearth of any accounting records, the Panel cannot determine what caused those variations.

15. Clinics

Novogenix received tissue from two PPLA clinics and an unknown number of unnamed clinics.[446] The firm signed its contract with the Planned Parenthood affiliate in 2010, but tissue donations started sometime in 2011 and ended in July 2015.[447]

[PP Doctor #1] stated that PPLA's contract with Novogenix was approved by PPFA's medical division.[448] That statement directly contradicts the testimony of [PP Witness #1] who testified that her department did not oversee fetal tissue donation contracts between affiliates and outside entities.[449]

b) Payments received by clinic

Under its contract with PPLA, Novogenix paid the PPFA affiliate $45 per donated specimen. The revenue documents created by the firm's counsel indicate that the between 2011 and July 2015, the firm paid PPLA a total of $52,965. As previously noted, because Novogenix did not provide primary source materials, the Panel cannot verify whether that figure is accurate.

[PP Doctor #1] stated that she "did [a] rough calculation of what the costs [to PPLA for consent of patients and the procurement of fetal tissue]" before she agreed to Novogenix's proposed $45 per specimen proposal. [PP Doctor #1] said she did not employ anyone to do an audit or retain an independent outside auditor, rather she consulted other PPFA affiliates, looked at the staff time involved in the following: triage; discussions with patients on fetal tissue donation; consent; her negotiations with Novogenix; and "parking spaces."[450]

The Panel is troubled by [PP Doctor #1]'s statements. None of the costs she cited are reimbursable under federal law.[451] In addition, a memorandum from PPFA's in-house counsel to all affiliate medical directors required that affiliates who participate in fetal tissue donation programs either accept no reimbursement or hire an independent auditor to calculate the affiliate's costs.[452] [PP Doctor #1] stated that, at the time PPLA entered into its contract with

[446] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015).
[447] *Id.*
[448] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[449] Unedited transcribed interview of [PP Witness #1] 145 (Oct. 6, 2016).
[450] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[451] 42 U.S.C. § 289g-2(e)(3).
[452] Memorandum from [PPFA Lawyer], et al. to Affiliate Chief Executives, Affiliate Medical Directors, Patient Service Directors, Re: Federal Regulations for Aborted Pregnancy Tissue Donation Programs (Apr. 4, 2001) [PPFA-HOU_E&C_00148–PPF-HOU_E&C-000150], Exhibit 5.45.

Novogenix, she knew they had received the memorandum and "was aware of it floating around in [her] head."[453] PPLA's blatant disregard for the memo on reimbursement for the cost of fetal tissue donation is the rule rather than the exception at PPFA affiliates (see "Planned Parenthood" section for a more detailed discussion on this issue).

16. Customers that Received Fetal Tissue from Novogenix

Novogenix received $170,980.59 from 7 research institutions between June 2011 and December 2015.[454] The Panel cannot determine the full universe of Novogenix's customers, or Novogenix' total revenue. Below is a list of Novogenix's known customers, and the amounts the customers paid the firm.

CLIENT	TOTAL PAID
University of Southern California	$100,995.89
University of California, Los Angeles	$ 58,299.89
City of Hope	$ 6,625.60
University of Connecticut Health Center	$ 2,138.56
Stanford University	$ 1,000.00
Children's Hospital of Philadelphia	$ 1,000.00
Rockefeller University	$ 960.65

17. Potential Violations of Law

c) Applicable Laws & Regulations

Novogenix was under not only a legal but also a contractual obligation to obey all laws: A provision of its contract with PPLA stipulated that "Novogenix agrees to conduct cell and stem cell research in compliance with all applicable federal and state laws."[455]

[453] [PP Doctor #1] briefing before the Committee on Energy and Commerce (Sept. 18, 2015), Exhibit 5.4.7.
[454] Panel analysis of invoices produced by Children's Hospital of Philadelphia; City of Hope; Rockefeller University; Stanford University; the University of Connecticut Health Center; the University of California, Los Angeles; and the University of Southern California.
[455] Specimen Donation Agreement between Novogenix Laboratories, LLC, and Planned Parenthood Los Angeles (Mar. 1, 2010), Exhibit 5.41.

i) 42 U.S.C. § 289g -2

The applicable federal law on fetal tissue is 42 U.S.C. § 289g-2(a), which states, "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." Under that law, "The term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[456] Human fetal tissue is defined broadly to include any "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth."[457]

ii) California Health and Safety Code Section 125320

The California Health and Safety Code contains virtually identical language to 42 U.S.C. § 289g-2. That law states that:

> (g) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.
>
> (h) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.
>
> (i) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.[458]

As with 42 U.S.C. § 289g-l(g), another provision of the California Health and Safety Code also broadly defines tissue to "mean a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body . . ."[459]

iii) HHS Regulations on Informed Consent

HHS requires investigators to obtain informed consent from each human being used as a research subject.[460] The "basic elements of informed consent" include the following information:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's

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[456] 42 U.S.C. § 289g-2(e)(3)
[457] 42 U.S.C. § 289g-l(g).
[458] Cal. Health & Safety Code § 125320.
[459] Cal. Health & Safety Code § 1635(c).
[460] 45 C.F.R. 46 § 116.

participation, a description of the procedures to be followed, and identification of any procedures which are experimental; . . . [and]

(2) A description of any benefits to the subject or to others which may reasonably be expected from the research . . .[461]

Federal regulations promulgated by HHS requires investigators to obtain informed consent from each human being used as a research subject.[462] There are eight basic elements of informed consent which, under the Common Rule, "shall be provided to each subject:"

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2) A description of any reasonably foreseeable risks or discomforts to the subject;

3) A description of any benefits to the subject or to others which may reasonably be expected from the researeh;

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.[463]

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[461] *Id.*
[462] 45 C.F.R. § 46.116.
[463] *Id.*

iv) HHS Regulations on Institutional Review Boards (IRBs)

HHS regulations require IRBs to "prepare and maintain adequate documentation" of its activities, including:

> (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
> (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
> (3) Records of continuing review activities. [and]
> (4) Copies of all correspondence between the IRB and the investigators.[464]

Those regulations only cover "clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products."[465] It is unclear whether any of the fetal tissue procured by Novogenix was used for any purpose covered by the regulations.

v) California Revenue and Tax Code

A provision of the California Revenue and Tax Code that states:

> [E]very retailer engaged in business in this state and making sales of tangible personal property for storage, use, or other consumption in this state, not exempted . . . shall, at the time of making the sales or, if the storage, use, or other consumption of the tangible personal property is not then taxable hereunder, at the time the storage, use, or other consumption becomes taxable, collect the tax from the purchaser and give to the purchaser a receipt therefore in the manner and form prescribed by the [California State Equalization Board].[466]

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[464] 45 C.F.R. § 46.115(a).
[465] 21 C.F.R. § 56.101(a).
[466] Cal. Rev. & Tax Code § 6203. A publication put out by the State Board of Equalization (SBE) states that provision applies to corporations, individuals, Limited Liability Companies, Limited Liability Partnerships, Limited Partnerships, partnerships, married co-owners, registered domestic partnerships, and organizations. Cal. State Bd. of

The law defines a "retailer engaged in business in" California as "Any retailer maintaining, occupying, or using, permanently or temporarily, directly or indirectly, or through a subsidiary, or agent, by whatever name called, an office, place of distribution, sales or sample room or place, warehouse or storage place, or other place of business."[467]

There is an exemption for the sale of human blood and human body parts.[468] However, Novogenix was not a tissue or blood bank. Rather it effectively sold fetal tissue cells, cell lines, and other products directly to customers. The California State Board of Equalization (SBE) recently collected nearly $82,000 for unpaid sales taxes for a non-profit organization that saves dogs, draws blood from those dogs, and sells the white blood cells, plasma, and red blood cells for transfusions into other canines.[469]

The statute defines tangible personal property as "personal property which may be seen, weighed, measured, felt, or touched, or which is in any other manner perceptible to the senses."[470] Thus, cells and cell lines are tangible personal property under the California Sales and Use Tax.

An SBE publication states that California companies can pass along the amount of sales tax to customers, provided the business lists a separate amount for sales tax reimbursement on its receipts or invoices, or if the sales agreement "specifically calls for the addition of sales tax reimbursement."[471] If the business includes sales tax reimbursement in its prices, companies "must inform the buyer that tax is included" by making one of the following statements on a price tag or in an advertisement: "All prices of taxable items include sales tax reimbursement computed to the nearest mill," or "The price of this item includes sales tax reimbursement to the nearest mill."[472] It is unclear whether Novogenix's contracts with its customers included those statements.

d) Findings

j) 42 U.S.C. § 289g-2 & California Health and Safety Code Section 125320

The Panel's investigation finds reason to believe that Novogenix may have violated 42 U.S.C. § 289g-2 and Cal. Health & Safety Code § 125320(a). The list of attorney-created

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Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 1.

[467] Cal. State Bd. of Equalization, "Laws, Regulations & Annotations, Sales and Use Tax Law, Chapter 3. The Tax," https://www.boe.ca.gov/lawguides/business/current/btlg/vol1/sutl/6203.html.

[468] Cal. Rev. & Tax Code § 33 ("Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.").

[469] Chris Haire, "Greyhound Dog Rescue Hemopet Fights to Stay Open after $82,000 Tax Bill," *Orange County Register*, Oct. 10, 2016, http://www.ocregister.com/articles/blood-731674-hemopet-greyhounds.html.

[470] Cal. Rev. & Tax Code § 6016.

[471] Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014, at 5.

[472] *See* Cal. State Bd. of Equalization, "Your California Seller's Permit: Your Rights and Responsibilities under the Sales and Use Tax Law," Pub. 72, May 2014,

Novogenix expenses included an unknown amount for attorney fees.[473] Such fees are not included under the list of allowable reimbursements under § 289g-2. The list of expenses also included minimal amounts for delivery to researchers.[474] Invoices produced to the Panel by Novogenix customers show the firm charged delivery fees of up to $122.43 per shipment.[475] The Panel questions whether that apparent contradiction indicates that Novogenix charged its customers more for transportation than it cost the firm.

ii) HHS Regulations on Informed Consent

Statements by [PP Witness #1] and documents produced by PPFA to the Panel indicate that Novogenix did not follow the HHS regulations on informed consent. The PPFA form the firm used to obtain consent to donate fetal tissue states:

> Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and more.
>
> . . . The benefits of consenting to donation today include furthering medical research in finding cures for disease like diabetes, leukemia, lymphoma, Parkinson's disease and more.[476]

That consent form specifically does not conform to the requirements for informed consent mandated under 45 C.F.R. § 46.116. Witnesses at a Panel hearing agreed that the PPFA form may not comply with the HHS regulations on informed consent.[477]

The requirements for informed consent further state that investigators "shall seek such consent only under circumstances that provide the prospective subject with . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."[478]

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[473] [Founder and Executive Director] Novogenix, briefing before Committee on Energy and Commerce (Sept. 3, 2015), Exhibit 5.42.
[474] *Id.*
[475] Panel analysis of invoices produced by Novogenix Laboratories, LLC.
[476] Planned Parenthood Federation of America, PPFA Manual of Medical Standards and Guidelines, Client Information and Informed Consent, Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment," Revised June 2011, Exhibit 5.44.
[477] *See* H. Comm. on Energy and Commerce, Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016. http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf
[478] 45 C.F.R. § 46.116.

iii) HHS Regulations on IRBs

Novogenix's counsel represented that the [Founder and Executive Director] was fully aware of the HHS IRB regulations.[479] Before he started the firm, the [Founder and Executive Director] had submitted proposals to an IRB.

Through that application process before the institutional review board, [Founder and Executive Director] was required to review and comply with certain rules and regulations and this developed an understanding of them. Such subjects included, but were not limited to the following:

- Anonymity [sic]
- Informed Consent [sic]
- Donation of fetal tissue for scientific research [sic][480]

The Panel has no evidence that Novogenix followed the HHS regulations on IRBs, despite [Founder and Executive Director]'s knowledge and understanding of the regulations.

iv) California Revenue and Tax Code

The Panel has uncovered evidence that shows Novogenix also may have violated the California Revenue and Tax Code. Novogenix sold its services to customers in California; it should have collected tax on those transactions. The Panel reviewed every invoice and purchase order that were provided by Novogenix's known California customers. Based on that review, there were 17 purchases by the University of Southern California upon which Novogenix did not charge the legally required sales tax.[481] What makes the missing sales tax more striking is that Novogenix did charge the required sales tax to all other purchases by the University of Southern California, as well as Stanford University, and the University of California, Los Angeles. A chart of those purchases is below (the Bates Stamp number column refers to the documents, as provided by the university).

[479] *See* Letter from Joshua A. Levy, Cunningham Levy LLP, to Charles Ingeberston, Chief Counsel, Committee on Energy and Commerce, Sept. 2, 2015, at 3.
[480] *Id.* at 2.
[481] Purchase orders produced by the Keck School of Medicine at the University of Southern California to the Panel Exhibit 5.46.

DATE OF PURCHASE ORDER	AMOUNT	SALES TAX	BATES STAMP NUMBER
3/12/2013	$ 1,700.00	0	KSM0001002
4/11/2013	$ 1,700.00	0	KSM0000978
5/20/2013	$ 2,450.00	0	KSM0000973
5/20/2013	$ 2,100.00	0	KSM0000968
8/30/2013	$ 700.00	0	KSM0000944
2/18/2014	$ 200.00	0	KSM0000888
5/14/2014	$ 1,000.00	0	KSM0000834
7/24/2014	$ 431.20	0	KSM0000781
7/24/2014	$ 629.60	0	KSM0000777
7/29/2014	$ 1,000.00	0	KSM0000768
8/20/2014	$ 630.40	0	KSM0001090
8/21/2014	$ 350.00	0	KSM0001086
9/29/2014	$ 431.20	0	KSM0001058
9/29/2014	$ 231.20	0	KSM0001054
10/9/2014	$ 231.20	0	KSM0001050
10/9/2014	$ 431.20	0	KSM0001046
10/27/2014	$ 1,000.00	0	KSM0001032
11/6/2014	$ 2,100.00	0	KSM0001028
11/13/2014	$ 229.60	0	KSM0001023

18. Conclusions

The Panel referred Novogenix' potential violations of 42 U.S.C. § 289g-2 to the U.S. Department of Justice. It referred Novogenix's possible violations of the California Health and Safety Law and the California Tax Revenue and Tax Code to the Los Angeles County District Attorney. Finally, the Panel referred Novogenix' potential violations of federal regulations on consent to the U.S. Department of Health and Human Services.

D. Advanced Bioscience Resources, Inc.

1. Summary

The Panel conducted an investigation of Advanced Bioscience Resources, Inc. (ABR) and uncovered evidence that ABR may have violated 42 U.S.C. § 289g-2 and the California Health and Safety Law.

a) Background of ABR

ABR, a non-profit corporate foundation, was started in 1989 as a resource for "biomedical, scientific, and educational purposes."[482] It "specializes in the procurement, preservation and distribution of both human fetal tissues and full term umbilical cord blood for research."[483] ABR obtains fetal tissue from abortion clinics and offers it to researchers for a fee.[484] ABR generally pays abortion clinics a flat per-tissue fee regardless of the type or amount of tissue procured. The tissue is obtained by tissue technicians embedded by ABR in abortion clinics. The technicians harvest, package, and ship the tissue to the researchers. The abortion clinic staff obtains consent from the patients for fetal tissue donations. ABR's business model is that of StemExpress. Notably the CEO of StemExpress began her career in the fetal tissue industry as a tissue technician at ABR.

b) History of the Panel's Interactions with ABR

On September 3, 2015, ABR responded to a document request by the House Energy and Commerce Committee.[485] When H. Res. 461 created the Panel on October 7, 2015, Energy and Commerce gave the Panel the production from ABR. Seeing the need for additional information, the Panel sent ABR a document request on January 21, 2016.[486] When ABR did not fully produce, the Panel issued a subpoena to ABR on April 29, 2016.[487]

The Panel and ABR's counsel came to a verbal agreement that ABR could respond to the subpoena on a rolling production basis. To date, ABR has still not fully complied with the

[482] Advanced Bioscience Resources, Inc., Production to the Subcommittee on Oversight and Investigations of the US House of Representatives Energy and Commerce Committee, Sept. 3, 2015 (HCEC000004), Exhibit 5.47.
[483] *Id.*
[484] *Id.*
[485] *Id.*, (HCEC000001), Exhibit 5.47.
[486] Document Request to Advanced Bioscience Resources, Inc. (Jan. 21, 2016), Exhibit 5.48.
[487] Subpoena to Advanced Bioscience Resourees, Inc. (Apr. 29, 2016), Exhibit 5.49.

subpoena. It has not produced bank records or internal communications and has fully redacted names from the documents it has produced.

2. ABR's Business Model

ABR obtains fetal tissue from abortion clinics and offers it for resale to researchers. It pays the clinics "a flat fee for services on a product of conception (POC) basis, regardless of how many, or what type, of specimens are procured . . . ."[488] The fees range from $45 to $60, depending upon the year and the clinic.[489] The tissue is obtained by ABR tissue technicians who are embedded in the abortion clinics; the technicians harvest, package, and ship the tissue to the researchers.[490] The abortion clinic staff obtains consent from the patients for fetal tissue donations.[491]

ABR represented that it does not have a website through which researchers request tissue. It is unclear whether that is accurate. Researchers apply for tissue through email. Applications are reviewed by senior ABR officials, including the president. The review is focused on the scientific creditability and feasibility of their studies. Onee approved, researchers send their specific tissue requests via facsimile, email, or phone call.

In order to harvest the tissue, ABR embedded tissue technicians within the abortion clinics. ABR has not yet produced sufficient documents for the Panel to determine how customers' tissue orders are communicated to the embedded technicians. The technicians' typical workday went as follows:

- The technicians contacted the clinics about the surgery schedule.
- They confirmed that the clinics had obtained consent from women undergoing abortions, either by speaking with clinic staff or by reviewing medical records. The clinics used an ABR consent form, similar to that used by StemExpress. The form states: "Recent advancements in medical research have been developed through the use of human tissues . . . Diseases such as diabetes, hemophilia, Parkinson's disease, cancer, AIDS, heart and lung diseases . . . are being investigated for the development of cures through the use of human fetal tissues."
- After the abortions were performed, the technicians identified and procured tissue per researchers' requests, placed the tissue in preservatives, packaged it, put it in shipping boxes, and delivered it to a courier or courier company.
- The technicians updated ABR on the tissue requests as they were fulfilled.

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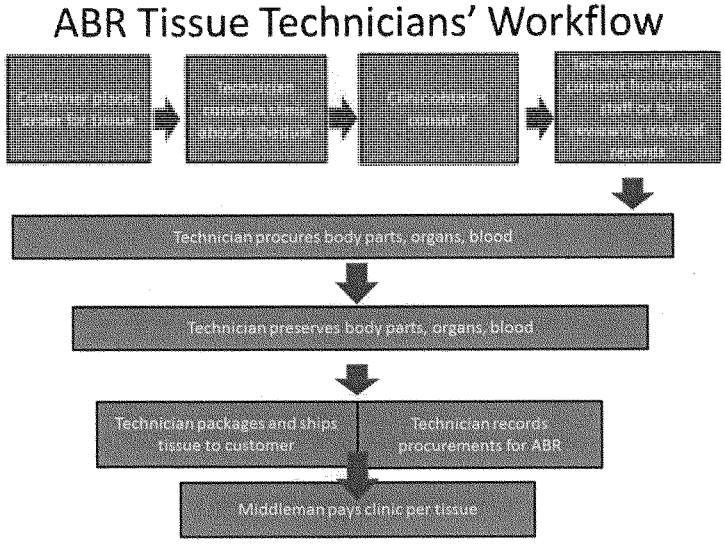
[488] Advanced Bioscience Resources, Inc., "ABR Overview: Key Points," at 5 (SP000752), Exhibit 5.50.
[489] Advanced Bioscience Resources, Inc., Production to the Subcommittee on Oversight and Investigations (HCEC000028 – 41), Exhibit 5.51.
[490] Advanced Bioscience Resources, at 7 (SP000754), Exhibit 5.50.
[491] *Id.* at 5.

- In contrast to the StemExpress case study, ABR employees are paid a salary or hourly wage and do not receive any bonus or other incentive payments based on the number or type of tissues they collect.[492]



3. ABR Payments to Abortion Clinics

According to productions made by 25 clinics from which ABR has received fetal tissue, ABR paid them a total of $1,002,147 from 2010 to 2015. ABR has only produced the payments it made in 2015, during which ABR made nearly $80,000 in payments to its top five abortion clinic sources from which it procured human fetal tissue. ABR paid the clinics' "costs for clinical staff obtaining consents, maintaining records, transferring fetal tissue, clinical space, and utilities."[493] The chart below shows ABR facility fee payments from 2010 through 2015 to the abortion clinics from which it obtained fetal tissue:

[492] Advanced Bioscience Resources, Inc., Production to the Subcommittee on Oversight and Investigations (HCEC000045), Exhibit 5.52.
[493] ABR Overview: Key Points at 5 (SP000752), Exhibit 5.50

CLINIC	TOTAL
Atlanta Women's Center	$ 1,972
Cherry Hill Women's Ccenter	$ 22,424
Choice Medical Group	$397,966
Downtown Women's Center, Inc	$ 4,550
Family Planning Specialist	$ 36,585
Feminist Women's Health Center	$ 300
Lovejoy Surgical Center	$ 135,565
M. Hanson	$ 28,970
Meadowbrook Women's Center	$ 13,585
Philadelphia Women's Center	$ 10,860
Planned Parenthood Riverside	$ 163,140
Planned Parenthood First Avenue	$ 145,315
Planned Parenthood Mar Monte (Sacramento)	$ 5,390
Planned Parenthood San Diego	$ 5,500
Pregnancy Consultation Center	$ 10,395
Whole Women's Health	$ 6,600

4. ABR Revenue from Customers

ABR's payments to the clinics should be contrasted with the amounts ABR has received from its customers. ABR produced payments from only a limited number of researchers to whom it transferred fetal tissue, covering invoices for a single year. Its production of invoices presents an incomplete picture of its income. ABR's income tax forms report $6.5 million in total revenue for the last five reporting years (2010-2014).

Pursuant to document request letters, researchers produced payments to ABR. According to these documents produced by the customers, ABR received $1,425,769.08 from the years 2010-2015. According to ABR's production, customers paid the non-profit $1,148,538.08 from

2010-2015. Therefore, according to the incomplete information the Panel has received, ABR received $423,622.08 more from customers than it paid to the clinics for the fetal tissue. Due to ABR's incomplete production, it is difficult to draw a complete conclusion based on these numbers. The chart below shows the amount of money ABR received from its customers:

Comparison of fetal tissue sales invoices obtained from ABR and directly from ABR's customers

Names of Customers	Produced by ABR			Produced by Customer			Variance
	2010-2015	2016	Total	2010-2015	2016	Total	Based on 2010-2015 Totals
All Cells LLC	27,405.08	-	**27,405.08**	27,405.08		**27,405.08**	-
Celula, Inc.	85,755.00	-	**85,755.00**	-		-	85,755.00
Childrens Hospital of Philadelphia	9,650.00	-	**9,650.00**	9,650.00		**9,650.00**	-
City of Hope	12,830.00	-	**12,830.00**	12,830.00		**12,830.00**	-
CO State University	20,100.00	-	**20,100.00**	-		-	20,100.00
Columbia University	27,940.00	-	**27,940.00**	185,430.00		**185,430.00**	(157,490.00)
Dartmouth	8,780.00	-	**8,780.00**	8,780.00		**8,780.00**	-
FDA/CDER	24,890.00	-	**24,890.00**	-		-	24,890.00
Johns Hopkins Medicine	-	-	-	1,020.00		**1,020.00**	(1,020.00)
Lonza Walkersville	23,835.00	-	**23,835.00**	-		-	23,835.00
Mass General Hospital	215,454.00	-	**215,454.00**	209,109.00		**209,109.00**	6,345.00
National Institute of Health	92,320.00	-	**92,320.00**	-		-	92,320.00
Rockefeller University	32,330.00	-	**32,330.00**	143,685.00		**143,685.00**	(111,355.00)
Samsung Biomed Res Inst	31,810.00	-	**31,810.00**	-		-	31,810.00
Sciencell Research Labs	21,840.00	-	**21,840.00**	-		-	21,840.00
Stanford University	-	-	-	7,860.00	1,220.00	**9,080.00**	(7,860.00)
SUNY Health Sciences Center	22,600.00	-	**22,600.00**	24,865.00		**24,865.00**	(2,265.00)
Temple University	-	-	-	26,140.00	1,835.00	**27,975.00**	(26,140.00)
University of CA SF	25,290.00	-	**25,290.00**	-		-	25,290.00
University of CA-LA School of Medicine	51,420.00	-	**51,420.00**	62,615.00		**62,615.00**	(11,195.00)
University of CT Health Center	1,280.00	-	**1,280.00**	1,280.00		**1,280.00**	-
University of MA Medical School	122,169.00	-	**122,169.00**	231,970.00	51,500.00	**283,470.00**	(109,801.00)
University of NC at Chapel Hill	155,120.00	-	**155,120.00**	286,280.00		**286,280.00**	(131,160.00)
University of PA Medical Center	50,460.00	-	**50,460.00**	132,295.00		**132,295.00**	(81,835.00)
Vertex Pharmaceuticals	40,870.00	-	**40,870.00**	-		-	40,870.00
Yale University Medical School	44,390.00	-	**44,390.00**	-		-	44,390.00
	1,148,538.08	-	**1,148,538.08**	**1,371,214.08**	**54,555.00**	**1,425,769.08**	

ABR transferred both human fetal tissue and body parts to researchers. Among those body parts were brains, hearts, eyes, skulls, eyes, spinal cords, spinal columns, and skin.

ABR 2015 Fetal Sales to Top 5 Customers Product and Totals

80 Fetal Brains totaling **$26,160**
51 past 20 weeks gestation

36 Pairs of Eyes totaling **$25,160**
15 past 20 weeks gestation

8 Hearts totaling **$2,720**
6 past 20 weeks gestation

16 Spinal Cords totaling **$5,100**
7 past 20 weeks gestation

2 Intact Calvarium totaling **$1,100**
1 past 20 weeks gestation

2 Spinal Columns totaling **$680**
1 past 20 weeks gestation

2 Skins totaling **$680**
Both past 20 weeks gestation

Summary Total for Top 5 Customers.....$61,600

5. ABR May Have Violated Federal and State Laws and Regulations

The Panel compared materials provided by ABR to § 289g-2, which prohibits receipt of valuable consideration for fetal tissue. Valuable consideration excludes costs "associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[494] Materials produced to the Panel by ABR created an unclear picture of their conduct and income. For example, ABR stated that it pays clinics "costs for clinical staff obtaining consents, maintaining records, transferring fetal tissue, clinical space, and utilities."[495] Only the costs of transfer of fetal tissue can offset valuable consideration. The same ABR document states that its tissue technicians procure the tissue, package it, and ship it.[496] When the Panel asked ABR whether it prepares tissue for research, or modifies it into cell lines, the firm's attorney stated "ABR does not provide any other services other than simple tissue procurement. . . ."[497]

[494] 42 U.S.C. § 289g-2(e)(3).
[495] Advanced Bioscience Resources, Inc., "ABR Overview: Key Points," at 5 (SP000752), Exhibit 5.50.
[496] *Id.* at 7.
[497] Letter from Jonathan F. Lopez, Orrick, Herrington & Sutcliffe, to Rep. Blackburn, Chairman, Select Investigative Panel 2 (Feb. 24, 2016), Exhibit 5.53.

Due to ABR's failure to produce a complete response to the Panel's subpoena and based on a thorough assessment of the information received, the Panel saw the need for a criminal investigation into ABR's fetal tissue practices. Therefore, the Panel sent criminal referrals to U.S. Attorney General Loretta Lynch and the District Attorney of Riverside County, California, urging them to conduct an investigation into whether ABR violated federal and state statutes and regulations, and to take appropriate action if the investigation reveals criminal behavior.

E. Human Fetal Tissue Repository

6. Summary

The Panel sought to determine whether the Human Fetal Tissue Repository (HFTR) fully complied with the applicable federal law and regulations. HFTR only produced a partial list of the entities from which it received and to which it distributed fetal tissue to the Panel. HFTR did not produce detailed accounting or eost documents to the Panel. As a result, the Panel had insufficient evidence to determine whether HFTR complied with the applicable federal law.

a) Background of the Human Fetal Tissue Repository

HFTR operated within the Albert Einstein College of Medicine ("Einstein") of Yeshiva University, located in The Bronx, New York.[498] HFTR began operations in March 1993.[499] Einstein's executive dean provided two different closure dates: He first told the Panel that HFTR closed on March 2, 2015.[500] The dean later told the Panel HFTR closed in September 2015.[501] The dean stated that in September 2015, Einstein's "operations were spun out from Yeshiva University to under [the] operational control of Montefiore Health Systems."[502]

The Panel sought to determine the disposition of the fetal tissue held by HFTR after its closure. The Panel had insufficient evidence to make that determination. However, there are indications that Einstein offered the tissue to the Planned Parenthood Federation of America (PPFA). [PP Witness #3] stated that after HFTR closed, "The people from Einstein came to visit us to see if [PPFA] would take over their repository."[503] The PPFA official added that Planned Parenthood abandoned the proposal because "It seemed like a lot of effort . . . ."[504]

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[498] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 1 (Feb. 10, 2016).
[499] Email from [Einstein Executive Dean], Albert Einstein College of Medicine, to Panel staff. (Nov. 27, 2016).
[500] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 1 (Feb. 10, 2016).
[501] *Id.* at 2.
[502] *Id.* at 1.
[503] Center for Medical Progress video FNND0569_ 20150226165708. The video was produced to the H. Comm. on Oversight and Government Reform pursuant to a subpoena. Panel staff viewed it under the terms of an agreement between the Chairman and Ranking Member of the H. Comm. on Oversight and Government Reform.
[504] *Id.*

HFTR received fetal tissue from three New York City hospitals, and it distributed the tissue to Einstein researchers and to fourteen other educational and research institutions.[505] HFTR received "reasonable payments associated with necessary activities such as transportation, processing, preservation, or quality control of the tissue" from the research institutions to which it provided fetal tissue.[506] The payments were $100 per sample for Einstein researchers and $250 per sample for outside researchers.[507] Documents produced by a research institution that received fetal tissue from HFTR show payments to HFTR of $250 per fetal tissue specimen.[508]

b) History of the Panel's Interactions with HFTR

On December 18, 2015, the Panel sent HFTR a document request letter asking for, among other items, a list of all entities from which it procured fetal tissue, a list of all entities to which it sold or donated fetal tissue, an organization chart, all communications that direct its employees to procure fetal tissue, all accounting records, and banking records related to the procurement, sale, donation, and distribution or shipment of fetal tissue.[509]

Einstein's response was delayed until after the production deadline of December 31, 2015, because after the closure of HFTR, the person to whom the letter was addressed was no longer employed by Einstein.[510] The Panel granted Einstein a production extension until January 31, 2016.[511] In the course of its review of HFTR records, Einstein discovered that it was missing all records for the period of January 2010 through July 2010.[512]

Einstein produced a list of entities from which it obtained and distributed fetal tissue to the Panel.[513] Einstein represented that it could not locate accounting records.[514] To date, the Panel has not received any communications that relate to fetal tissue or any accounting or banking records.

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[505] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 1-2 (Feb. 10, 2016).
[506] *See id.* at 1.
[507] *See id.* at 2.
[508] Invoices produced by the University of Connecticut Health Center to the Panel [000005-000007], Exhibit 5.54.
[509] *See* Letter from Rep. Marsha Blackburn, Chairman, House Select Investigative Panel, to [HFTR Official] (Dec. 18, 2015).
[510] Email from [Einstein Vice-President, Government and Community Relations], Albert Einstein College of Medicine of Yeshiva University, to Panel staff (Jan. 12, 2016).
[511] Telephone conference between [Einstein Vice-President, Government and Community Relations], Albert Einstein College of Medicine of Yeshiva University, and Panel staff (Jan. 12, 2016).
[512] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 2 (Feb. 10, 2016).
[513] Documents produced by Albert Einstein College of Medicine of Yeshiva University to the Panel (Jan. 27, 2016) [hereinafter Documents produced by Albert Einstein], Exhibit 5.55.
[514] Telephone conference between [Einstein Vice-President, External Affairs], Albert Einstein College of Medicine of Yeshiva University, and Panel staff (Jan. 27, 2016).

7. Hospitals from which HFTR Procured Fetal Tissue

HFTR did not procure fetal tissue directly from abortion clinics; rather, it "received" tissue from Jacobi Medical Center, North Central Bronx Hospital, and Weiler Hospital.[515]

8. Procurement Process

The Panel sought to determine HFTR's procurement procedures, including whether it had contracts with the hospitals from which it procured fetal tissue. Due to the lack of records provided by Einstein, the Panel had insufficient evidence to determine whether HFTR had contracts with those medical facilities; how much, if any anything, HFTR paid for the tissue; whether the hospitals or HFTR obtained consent; how the consent was obtained; and the content of the consent form.

The Panel sought to determine the number of women from which HFTR obtained fetal tissue and the number of fetal tissue samples HFTR obtained. Documents produced by Einstein to the Panel show that a total of 2,701 "subjects" were "enrolled" in HFTR studies.[516] The Panel had insufficient evidence to determine the number of fetal tissue samples HFTR obtained.

Documents produced by the University of Wisconsin School of Medicine and Public Health (UW SMPH) to the Panel show that HFTR required detailed information from each of its potential customers. HFTR sent each applicant a letter that listed the information it required. The letter stated:

> In order to expedite your request, please provide [HFTR] with [the] following information:
>
> - An abstract and brief summary of your IRB-approved human experimentation protocol. Clearly state which tissues you will use for your study and why you must use human tissues – and human *fetal* tissues in particular.
> - A copy of your local IRB approval letter. When filing out your IRB application, be sure to state that you will be receiving tissue from [HFTR].
> - Please read and sign the enclosed Risk Handling Statement.
> - Please read and sign the Non-Transplant Fetal Tissue Request Form. . . . These agreements emphasize several issues:
>
> 1. You are responsible for understanding and adhering to appropriate safety standards for the protection of yourself and laboratory personnel under your supervision who will be handling the human tissue.

[515] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] (Feb. 10, 2016).
[516] Documents produced by Albert Einstein, Exhibit 5.55.

2. Unless you are licensed to do so by New York State, you may not distribute any portion of the tissue disbursement or products derived therefrom to colleagues or other investigators.[517]

The Non-Transplant Fetal Tissue Request Form stated that researchers who received fetal tissue from HFTR agreed to use the specimens "in compliance with all applicable standards and regulations, including, but not limited to those relating to research involving human and animal subjects . . ."[518] The form further stated that researchers "will pay a transmittal fee of $250 per sample to reimburse [HFTR] for its preparation and distribution costs."[519]

In addition to the non-transplant fetal tissue request form, HFTR required researchers to sign a Material Transfer Agreement, which stated in part that the fetal tissue "IS NOT FOR USE IN HUMAN SUBJECTS," and "will be used for teaching or for not-for-profit research purposes only."[520]

9. Researchers that Received Fetal Tissue from HFTR

The incomplete documents produced by Einstein to the Panel show that HFTR distributed fetal tissue to fourteen research institutions. The Panel had insufficient evidence to determine whether the list below, which was compiled from Einstein's incomplete production, encompasses the entire universe of research institutions that received fetal tissue from HFTR:

- Montreal Neurological Institute
- University of California, Irvine
- New York University School of Medicine
- Memorial Sloan-Kettering Cancer Center
- Yale University School of Medicine
- Wayne State University School of Medicine
- Rockefeller University

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[517] Albert Einstein College of Medicine of Yeshiva University, Human Fetal Tissue Repository (Dec. 15, 2010), produced by the University of Wisconsin-Madison School of Medicine and Public Health to the Panel (emphasis in original) [0171], Exhibit 5.56.

[518] Documents produced by Albert Einstein, Exhibit 5.55.

[519] *Id.*

[520] Albert Einstein College of Medicine of Yeshiva University, Material Transfer Agreement for Transfer of Material to Academic, Non-Profit Organizations (Sept. 3, 2009), produced by the University of Wisconsin-Madison School of Medicine and Public Health to the Panel [0172] (emphasis in original), Exhibit 5.57.

- University of Connecticut Health Center
- University of Virginia
- Johns Hopkins
- State University of New York, Buffalo
- University of Wisconsin
- University of Medicine and Dentistry of New Jersey
- Children's National Medical Center[521]

The Panel sought to determine the number of fetal tissue samples each research institution received and the amount of money that HFTR received from those institutions. Due to Einstein's lack of production, the Panel lacked sufficient evidence to make such a determination.

10. Conclusions

HFTR produced a limited set of documents to the Panel. Among the types of documents that HFTR did not produce were accounting records. Thus, the Panel has insufficient evidence to determine the cost to HFTR for the transportation, processing, preservation, quality control, or storage of fetal tissue. The Panel has insufficient evidence to determine the total amount that HFTR received from the research institutions that obtained tissue from the repository.

Documents produced by HFTR to the Panel show that it required researchers to submit summaries of their IRB-approved protocols, and copies of their IRB approval letters. Those documents show HFTR also required researchers to state what tissues they will use for their study, why they must use human tissue generally, and fetal tissue in particular. The documents produced by HFTR to the Panel show the repository required researchers who applied to receive fetal tissue to use the samples in compliance with all applicable laws and regulations, including the HHS regulations on research that involves human subjects.

Based solely on HFTR's limited productions, The Panel determined it appears that HFTR complied with the applicable HHS regulations, or at least made an attempt to do so. The Panel has insufficient evidence to make a conclusive determination whether HFTR and the research institutions to which it supplied fetal tissue fully complied with the HHS regulations.

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[521] Letter from [Einstein Executive Dean], Albert Einstein College of Medicine, to Rep. Marsha Blackburn, Chairman, Select Panel on Fetal Lives [sic] 1 (Feb. 10, 2016). *See generally* documents produced by Albert Einstein College of Medicine of Yeshiva University (Jan. 27, 2016).

VII. Case Studies of the Fetal Tissue Industry—The University/Clinic Model

Chapter VI Redaction Key:

1. [Clinic A Dr. #1] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.
2. [Dr. Administrator] is a faculty member of the University of New Mexico.
3. [NM Doctor #2] is a faculty member of the University of New Mexico.
4. NM Doctor #3] is a director of Southwestern Women's Options and a faculty member of the University of New Mexico.
5. [NM Doctor #4] is a faculty member of the University of New Mexico.
6. [NM Doctor #5] is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.
7. [NM Doctor #6] is an employee of Southwestern Women's Options.
8. [Dr. Administrator #2] is a faculty member of the University of New Mexico.
9. [NM Research Doctor] is a faculty member of the University of New Mexico.
10. [NM Patient] was a patient at Southwestern Women's Options.
11. [WA Clinic Director] Executive Director and co-founder of the Cedar River Clinics.
12. [WA Doctor #1] is a faculty member at the University of Washington and also works at the Cedar River Clinics.
13. [WA Doctor #2] is a physician who works at the Cedar River Clinics.
14. [WA Doctor #3] is a faculty member at the University of Washington and also works at the Cedar River Clinics.
15. [WA Doctor #4] is a faculty member at the University of Washington and also works at the Cedar River Clinics.
16. [WA Doctor #5] previously worked at the Cedar River Clinics while a faculty member at the University of Washington.

17. [WA Doctor #6] is a former University of Washington resident who worked at the Cedar River Clinics and currently works at the Swedish Medical Center.

18. [WA Doctor #7] is a former University of Washington resident who worked at the Cedar River Clinics and currently works at Northwest Women's Healthcare.

19. [WA Doctor #8] is a faculty member at both the University of Washington and Northwestern University and owner and operator of All Women's Health-North.

20. [WA Doctor #9] is a physician who formerly worked at the Cedar River Clinics and now works at All Women's Health-North.

21. [WA Patient] was a patient at the Cedar River Clinics who filed a medical malpractice suit against [WA Doctor #2] for injuries alleged following an abortion performed at 25+ weeks.

22. [WA Doctor #10] is a former resident and current faculty member at the University of Washington who served as medical director of the Planned Parenthood of Greater Washington and North Idaho.

23. [WA Doctor #11] is a faculty member at the University of Washington and also works at the Planned Parenthood of Greater Washington and North Idaho.

24. [WA Research Doctor #1] is a faculty member at the University of Washington and the author of the university's Birth Defects Research Lahoratory's NIH grant proposals.

25. [WA Research Doctor #2] is a research scientist at the University of Washington who has participated in fetal tissue research studies.

26. [WA Research Doctor #3] is a former resident at the University of Washington who has participated in fetal tissue research studies.

27. [WA Research Staff] is a technical operations manager at the University of Washington School of Medicine's WWAMI Institution for Simulation in Healthcare. He has participated in fetal tissue research studies.

28. [WA Administrator] is an administrator in the University of Washington's government relations office.

29. [PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.

30. [PP Witness # 2] is a manager of research projects at Planned Parenthood Gulf Coast (PPGC).

31. [PPFA Lawyer] is a legal official at PPFA.

32. [PPFA Medical Officer #1] is a PPFA official who was responsible for medical issues.

33. [PPFA Medical Officer #2] is a PPFA official who was responsible for medical issues.

34. [PPGC Abortion Services Official] is a manager of abortion services at PPGC.

35. [PPGC Abortion Doctor] is a doctor who performed abortions at PPGC.

36. [PPGC Staff] is a PPGC staff worker who assisted in the abortion clinic.

37. [UTMB Researcher # 1] is a researcher at the University of Texas Medical Branch who worked with PPGC on fetal tissue procurement.

38. [PPGC Executive] is the director of abortion services and medical director at PPGC.

39. [UTMB Researcher #2] is a second researcher at the University of Texas Medical Branch who worked with PPGC on fetal tissue procurement.

40. [UTMB Staff] is a UTMB staff worker who administers contracts for researchers.

41. [BCM Researcher] is a researcher at the Baylor College of Medicine who worked with PPGC on fetal tissue procurement.

42. [BCM Staff] is a staff employee at the Baylor College of Medicine who worked with PPGC on fetal tissue procurement.

43. [BCM Contract Manager] is an employee of the Baylor College of Medicine who manages contracts.

44. [MO Doctor #1] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

45. [MO Doctor #2] is Planned Parenthood of the St. Louis Region and Southwest Missouri's pathologist and the owner of Pathology Services, Inc.

46. [MO Doctor #3] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

47. [MO Doctor #4] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

48. [MO Doctor #5] is a faculty member of the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

49. [MO Doctor #6] is or was a clinical fellow in the Ob/Gyn department of the Washington University School of Medicine and also works at Planned Parenthood of the St. Louis Region and Southwest Missouri.

50. [WI Doctor #1] was an assistant professor of Ob/Gyn at the University of Wisconsin, School of Medicine and Public Health, while serving as the associate medical director of Planned Parenthood of Wisconsin.

51. [WI Doctor #2] is the director of the Ryan Fellowship and a member of the Ob/Gyn faculty at the University of Wisconsin, School of Medicine and Public Health, and also works at Planned Parenthood of Wisconsin.

52. [MI Doctor] is both an associate professor in University of Michigan's Ob/Gyn department and medical director for Planned Parenthood in Ann Arbor.

A. Summary

The Panel identified several research institutions across the United States, most of them state universities and virtually all of them recipients of federal as well as state funding, that have formed a close relationship with one or more abortion clinics. They regularly acquire tissue from those clinics for research purposes and in some cases distribute fetal tissue to other research institutions. Typically, the research institution requests specific human fetal organs or tissue, of a specific gestational age, from an abortion clinic, and the clinic informs the research institution when they have abortions scheduled that may produce the desired human body parts. Over time, the clinic learns which human fetal organs and tissue are useful to the research institution and often alerts the research institution to their availability without prior solicitation. Once available, the research entities make arrangements to transfer the fetal organs and tissue from the clinic. In some cases, the research institutions also have relationships with tissue procurement companies. In still other cases, partnerships do not involve the transfer of fetal tissue between the clinics and universities, but they share medical school faculty and residents in common, raising additional issues about the role of government-funded institutions in providing abortions and driving the demand for fetal tissue. The Panel sought to understand these and other factors relevant to its analysis of fetal tissue transactions under 42 U.S.C. § 289g-2 and to determine what role, if any, government funding plays in the transactions between abortion clinics and universities.

B. The University of New Mexico, Southwestern Women's Options, and Planned Parenthood

8. Summary

The Panel's investigation examined the relationship between the University of New Mexico and a late-term abortion clinic near the university. A tissue technician employed by the University of New Mexico (UNM) traveled frequently to Southwestern Women's Options (SWWO), a clinic located one mile from UNM that performs abortions through the third trimester, to procure human fetal organs or tissue an average of 39 times a year since 2010. Additionally, several UNM medical faculty were scheduled on a weekly basis to perform abortions at a local Planned Parenthood affiliate.

The Panel submitted document requests to UNM and SWWO on January 6, 2016. Following both entities' refusal to make a complete production,[522] the Panel issued subpoenas dated February 12, 2016. The Panel conducted depositions of [Clinic A Dr. #1] of SWWO on May 6, 2016, and of [Dr. Administrator] of UNM on May 11, 2016. The Panel sought to understand whether the safeguards anticipated by § 289g-2 were in place, including whether too close a relationship might be formed between an abortion clinic and researchers. In the course of its inquiry, the Panel uncovered a lattice work of close connections between UNM and SWWO. SWWO is the sole provider of fetal tissue to UNM, and according to [Dr. Administrator], no fetal tissue resulting from abortions performed at UNM are donated for fetal tissue research.[523]

The transfer of fetal tissue from SWWO to UNM was only one part of a much larger regime of activities whereby UNM aggressively expanded abortion advocacy and services in New Mexico. In a concerted and organized effort, the offices, personnel, and resources of UNM and, in particular, leadership personnel at UNM medical school: (1) expanded UNM's role both in providing abortions and in training new abortion doctors; (2) expanded UNM's referral for abortion services to outside clinics, including the clinic from which it obtained fetal tissue; (3) supplied residents and fellows to perform abortions for SWWO during the period that UNM was obtaining fetal tissue from that clinic; (4) expanded the faculty of UNM by providing "volunteer faculty" status to local abortion practitioners; (5) provided staff physicians for the Planned Parenthood in Albuquerque from UNM faculty after that clinic transitioned from one owner to another; and (6) leveraged their status to organize UNM employees and students for partisan political activities.

UNM has stated that the fetal tissue transferred from SWWO is of great value to its research department. But this close relationship led to shoddy clinical practices. For example, while a UNM consent form for fetal tissue donation does exist, testimony obtained by deposition and affidavit revealed that the form is not regularly used and that SWWO improperly combines consent for tissue donation with consent for the underlying abortion procedure. In a second

[522] *See* Chapter XI *infra*.
[523] Transcript of Deposition of [Dr. Administrator], May 11, 2016 ([Dr. Administrator] Tr.), at 44, 187.

example, neither UNM nor SWWO appears to have any apparatus or procedure to aid those infants who survive the abortion procedure.[524]

Documentation obtained by the Panel in the course of its investigation shows that the transfer of fetal tissue from SWWO to UNM for research purposes is a systematic violation of New Mexico's Jonathan Spradling Revised Uniform Anatomical Gift Act (Spradling Act). These violations occurred as UNM personnel procured fetal tissue from patients at SWWO for research by UNM entities. The Panel accordingly made a criminal referral to the Attorney General of New Mexico recounting evidence of violations of law involved in the transfer and use of fetal tissue between UNM and SWWO.

Based on a procurement log attached to that referral, a former patient at SWWO discovered that her aborted infant's remains were likely transferred to UNM for research. Because UNM and SWWO had not given her the opportunity to give informed consent required under 42 U.S.C. § 289g-1, 45 C.F.R. 46, and New Mexico's Maternal, Fetal and Infant Experimentation Act, the Panel followed with a second criminal referral to the Attorney General of New Mexico.

9. The University of New Mexico Becomes an Abortion Provider

Before 2000, neither the UNM Hospital nor any of its clinics offered abortions except in limited circumstances. Abortions were not performed except in rare cases of fetal anomaly or certain threats to a pregnant woman's health—and then only in the hospital's labor and delivery or operating rooms. When abortions were performed, nursing personnel and anesthesiologists often were unwilling to participate.[525]

UNM's practice changed dramatically following the efforts of an abortion policy committee—largely spearheaded by [Dr. Administrator] and [NM Doctor #2], respectively, faculty members of the university's departments of Obstetrics and Gynecology (Ob/Gyn) and Family Medicine—to have UNM become a provider of abortions beyond the former limited circumstances. The doctors' objective met with opposition from upper-level UNM Hospital administrators, who told them that UNM policy prohibited abortions at university clinics, that the hospital would not subsidize abortion, and that nurses would not want to participate in any aspect of abortion. Over the course of about a year and a half, the doctors pressed ahead with their agenda, disregarding the admonitions of administrators and reservations of most of the hospital staff who did not wish to be implicated in abortion practice. In 2002, the doctors succeeded in introducing medical abortion—through the use of mifepristone, or RU-486—into UNM clinics.[526]

The doctors then pressed further, against additional resistance by administrators, until they successfully introduced surgical abortion into UNM clinics. To do this they overrode

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[524] *See* Chapter VII.E *infra*.

[525] [redacted], [redacted]. "*You Can't Do That 'Round Here': A Case Study of the Introduction of Medical Abortion Care at a University Medical Center*, 71 Contraception 84, 84-85 (2005) [hereinafter *You Can't Do That*].

[526] *Id.* at 84-88; [Dr. Administrator] Tr. at 140-41.

objections of clinic staff, despite acknowledging that such opposition "may be intense, particularly due to the more extensive patient interaction required for surgical procedures and the increased complexity of the procedure." By that point, however, the doctors, whose salaries are paid by the taxpayers of New Mexico, were disinclined to accommodate such moral qualms, dismissively writing in a published article that while they "anticipate hiring dedicated nurses and support staff . . . . abortion opponents have limited rationale to prevent MVA [manual vacuum aspiration] for pregnancy termination."[527] Today, UNM Hospital performs surgical abortions for any reason through 25 weeks gestation.[528] At or beyond 24-25 weeks gestation, "pregnancy termination will be considered on a case-by-case basis for maternal or fetal reasons."[529] [Dr. Administrator] testified that "[t]here are situations where third trimester terminations take place" at UNM Hospital, when there is "a maternal indication or a fetal indication."[530] Such an indication could include a diagnosis of Down Syndrome.[531] At the UNM Center for Reproductive Health, surgical abortions are offered from the time when a pregnancy is first identified through 23 weeks gestation, and medical abortions are offered up to 10 weeks gestation.[532] UNM also refers patients to SWWO and to clinics in Colorado and Maryland, the Boulder Abortion Clinic and Germantown Reproductive Health Services, for late-term abortions.[533]

The advocacy that introduced UNM's practice of medical and surgical abortion did not occur as an initiative of activist faculty only. Grants from the Susan Thompson Buffett Foundation provided funding to promote the expansion of abortion at UNM, including the training of both faculty and students at UNM to become abortion providers.[534] Such training occurred through programs like the Center for Reproductive Health Education in Family Medicine for Family Medicine residents and the Kenneth J. Ryan Residency Training Program for Ob/Gyn residents.[535]

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[527] *You Can't Do That* at 88.

[528] For examples of protocols regarding surgical and medical abortions offered at UNM during the first trimester, see UNM Health Sciences Center, Medical Abortion [UNM01681], Exhibit 6.1; UNM Health Sciences Center, Management of Very Early Pregnancy Medical and Surgical Abortion [UNM01689-UNM01691], Exhibit 6.2. Abortions performed during the second trimester are either dilation and evacuation (D&E) or induction of labor. UNMHSC, Second Trimester Pregnancy Termination, D&E and induction of labor, Exhibit 6.3.

[529] UNMHSC, Second Trimester Pregnancy Termination, D&E and induction of labor [UNM01685], Exhibit 6.3.

[530] [Dr. Administrator] Tr. at 46.

[531] [Dr. Administrator] Tr. at 57.

[532] UNM Center for Reproductive Health, Abortion Care, http://unmmg.org/clinics/crh/abortion-care/index.html, Exhibit 6.4.

[533] [Dr. Administrator] Tr. at 46-47.

[534] The Susan Thompson Buffett Foundation 990-PF reports, Exhibit 6.5; [Dr. Administrator] Tr. at 128-29, 132-33. While the Foundation was the source of funds for this fellowship, Berkshire Hathaway is by means of a sole proprietorship the owner of Danco Laboratories, the sole distributor of mifepristone and the entity from which UNM would obtain the medication when it undertook medical abortions. [Dr. Administrator] Tr. at 137-39.

[535] *You Can't Do That*, at 85-86. These two programs and a third—the Access Project, which according to [Dr. Administrator] is a part of the Center for Reproductive Health Education in Family Medicine—entail three grants for student programs that involve abortion. The Susan Thompson Buffett Foundation funds all three. [Dr. Administrator] Tr. at 134-36.

10. UNM Provides Doctors to Southwestern Women's Options and Planned Parenthood

The doctors of UNM's Ob/Gyn department, with financial support from the Susan Thompson Buffett Foundation, formed the UNM School of Medicine Fellowship in Family Planning (UNM Fellowship), which served as the vehicle by which UNM medical residents were deployed to the nearby Albuquerque abortion clinics—SWWO and Planned Parenthood—to provide abortions. While, like any university fellowship, the UNM Fellowship had an educational purpose, its "major goal" was to send UNM doctors to SWWO in order to "give additional volume of 2nd trimester abortions" under the supervision of [NM Doctor #3] of SWWO.[536] [Dr. Administrator] initiated the training rotation with SWWO.[537]

The Panel obtained two UNM contracts with SWWO that provide for UNM residents to supply staffing at the clinic. One contract is a single-page "program letter of agreement" covering July 1, 2011, to June 30, 2012. It was not signed until January 2012, and the sole UNM signatory was the program director of UNM's Family Medicine Residency Program.[538] The other contract totals two pages, covers the two-year period beginning July 1, 2014, and describes assignments by which UNM fellows would perform abortion procedures at SWWO in two "two-week rotations."[539] These rotations were entirely dedicated to training the fellows to competency in the performance of the abortion procedure.[540] The sole UNM signatory to this contract was the director of the UNM Fellowship, [Dr. Administrator].

Neither the 2012 nor the 2014 contract was signed by an official with signature authority under UNM policy, and neither contract indicates that it was reviewed by a contract review officer in the University Counsel's Office, another UNM policy requirement.[541] The "resident rotation" was a large-scale program at UNM, according to [Dr. Administrator]. "All of the interns rotate through, unless they opt out. So we do a very large scope of training." Additionally, the "physician assistant and nurse practitioner and nurse midwifery programs have asked us to take nursing students, which we accommodate when we can."[542]

Under the New Mexico Tort Claims Act, UNM faculty, students, and residents had their malpractice insurance provided by the state for their work at outside abortion clinics, including

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[536] UNM-SWWO agreement (June 2, 2014) [UNM03417-UNM03418] [hereinafter 2014 UNM-SWWO agreement], Exhibit 6.6.
[537] [Dr. Administrator] Tr. at 173-74.
[538] UNM-SWWO agreement signed Jan. 5 and Jan. 7, 2012 [UNM03419], Exhibit 6.7.
[539] 2014 UNM-SWWO agreement. In her deposition, [Dr. Administrator] testified that fellows would train for between two and six weeks. [Dr. Administrator] Tr. at 189.
[540] [Dr. Administrator] Tr. at 189; Transcript of Deposition of [Clinic A Dr. #1], May 6, 2016 ([Clinic A Dr. #1] Tr.), at 86-88.
[541] *See* University of New Mexico Regents' Policy Manual, Section 7.8: Signature Authority for Contracts, Exhibit 6.8; Administrative Policies and Procedures Manual, Section 5.2, Exhibit 6.9; University Business Policy 2010 Exhibit B2, Exhibit 6.10. When questioned about this deficiency in the UNM-SWWO contracts, [Dr. Administrator] testified that what the university had with SWWO was in fact "a program letter" and "not a contract." [Dr. Administrator] Tr. at 147. She proceeded to admit that the "program letter . . . defines the educational expectations of the fellow . . . when they do this rotation and the expectations of the preceptor." *Id.* at 148. Such a document setting forth mutual expectations would plainly seem to meet the legal definition of a contract.
[542] [Dr. Administrator] Tr. at 87-88.

SWWO and Planned Parenthood.[543] Neither SWWO nor Planned Parenthood provided fellows any compensation.[544] They received their entire compensation from UNM.[545]

[Clinic A Dr. #1], who participated in the fellowship while employed by UNM, testified that she spent four weeks—broken into two two-week shifts—at SWWO and up to another 20 days at Planned Parenthood.[546] During her fellowship, she was trained in the performance of the abortion procedure by [Dr. Administrator] and by at least two SWWO doctors.[547] In a given week, which consisted of a full-time work schedule at the clinic, she estimated she might see 30 patients.[548] After her fellowship ended, she joined the staff of SWWO, where she has worked full time since 2014, alternating between SWWO's Albuquerque clinic and a second clinic it operates in Dallas, Texas, where abortions are allegedly not performed beyond 21 weeks and six days gestation.[549] During the four weeks of her fellowship at SWWO in Albuquerque, she testified she performed or assisted in approximately 10 to 15 third-trimester abortions.[550] Including that number and factoring in her subsequent employment by the clinic, she estimated she performed over the course of her work at SWWO in Albuquerque a total of possibly more than 50 third-trimester abortions.[551] Considering that [Clinic A Dr. #1]'s employment at SWWO has been based mostly in Dallas, which allegedly does not provide third-trimester abortions, and that she spent only about a quarter of one year (2015) working at the Albuquerque location,[552] her estimate suggests a particularly high volume of third-trimester abortions at SWWO in Albuquerque.

Since the time when opposition to participating in abortion procedures was the predominant view of UNM medical staff, the culture appears to have changed, along with the composition of UNM hospital and clinic personnel, to one aggressively in favor of the expansion of abortion. [Dr. Administrator], [NM Doctor #4], and other UNM medical faculty members engage in political fundraising and lobbying for an expansion of abortion services and public funding in support thereof. [Dr. Administrator] herself has held leadership positions the last five years in the American College of Obstetricians and Gynecologists (ACOG) and the Society of Family Planning.[553] She testified that "advocacy is . . . a core requirement in our training program," one that falls under the ACGME accreditation requirements for Ob/Gyn residents.[554] UNM students are encouraged to participate in such activities as ACOG Lobby Day, the New Mexico Lobby Day, and the Congressional Leadership Conference, which are organized by

[543] [Dr. Administrator] Tr. at 151-54; [Clinic A Dr. #1] Tr. at 152.
[544] [Clinic A Dr. #1] Tr. at 92, 94-95, 97-98, 103.
[545] [Clinic A Dr. #1] Tr. at 97-98, 102-103.
[546] [Clinic A Dr. #1] Tr. at 86-88, 92-93. [Clinic A Dr. #1] recalled her compensation from UNM was "in the low fifties" at the time of her fellowship. *Id.* at 102.
[547] [Clinic A Dr. #1] Tr. at 89-91. [Clinic A Dr. #1] was already fully board certified at the time of her fellowship. [Clinic A Dr. #1] Tr. at 102.
[548] [Clinic A Dr. #1] Tr. at 147, 158-59.
[549] [Clinic A Dr. #1] Tr. at 266.
[550] [Clinic A Dr. #1] Tr. at 150, 247.
[551] [Clinic A Dr. #1] Tr. at 247.
[552] [Clinic A Dr. #1] Tr. at 266 (testifying that her employment at SWWO was exclusively in Dallas except for alternating weeks between there and Albuquerque between January and approximately July of 2015).
[553] [Dr. Administrator] Tr. at 126.
[554] [Dr. Administrator] Tr. at 141.

ACOG.[555] Meanwhile, the once-majority view among UNM medical personnel appears to have been marginalized, if not punished outright. In January 2016, a medical student filed a lawsuit against the UNM Board of Regents alleging that he was referred to a disciplinary committee by [Dr. Administrator] and sanctioned by UNM for posting his personal views against abortion on his Facebook page, despite the fact that the posts did not mention UNM.[556]

During the summer of 2015, amid the national news coverage of practices of abortion clinics and tissue procurement companies with respect to the handling and possible sale of fetal tissue, UNM fell under increased scrutiny. Members of the New Mexico state legislature began to investigate UNM's relationship with SWWO and the handling of fetal tissue, as did a private organization, the New Mexico Alliance for Life, and the *Albuquerque Journal*.[557] In a terse letter from [Dr. Administrator] to [NM Doctor #3] dated December 14, 2015, the UNM Fellowship program at SWWO was terminated, despite the fact that more than six months remained under the 2014 contract.[558] [Dr. Administrator] testified the termination occurred after a review conducted by the UNM Fellowship determined the fellows "did not have the volume of second trimester pregnancy terminations that were required for competency,"[559] but it is difficult to dispute that the timing of UNM's decision was related to the various investigations.

UNM's contracts with Planned Parenthood are referred to as "house officer affiliation agreements" and contain eight pages that provide details of the "close working relationship between the University" and Planned Parenthood, largely in the form of providing resident UNM physicians to staff the clinic.[560] Over the course of its relationship with UNM, the Planned Parenthood of New Mexico located in Albuquerque was acquired by Planned Parenthood of the Rocky Mountains, after which UNM staffed the Albuquerque Planned Parenthood location not only with fellows, but also with doctors from its Ob/Gyn department to serve as staff physicians.[561] Attached as an illustration of this relationship is a schedule generated by the department for the month of May 2016 detailing rotations at the clinic for staff physicians from UNM.[562]

11. UNM Confers Faculty Status and Benefits upon SWWO Personnel

Most of the doctors employed on the staff of SWWO also have what are described as "volunteer faculty" positions at UNM. [NM Doctor #3] is a clinical assistant professor in the Ob/Gyn department. [Clinic A Dr. #1] transitioned from employment at UNM to employment at

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[555] [Dr. Administrator] Tr. at 123. *See also* ACOG legislative activities update screenshot (May 2013), Exhibit 6.11 (noting an ACOG event attended by 60 "Fellows, Junior Fellows, and medical students").
[556] Complaint at 2, 6, 8-10, Hunt v. Board of Regents of the University of New Mexico, No. D-202-CV-2016-00143 (N.M. Dis. Ct., Bernalillo Co., Jan. 15, 2016).
[557] Colleen Heild, *UNMHSC Halts Training at Private Abortion Clinic*, Albuquerque Journal, Dec. 20, 2015, at A1.
[558] Letter from [Dr. Administrator] to [NM Doctor #3], (Dec. 14, 2015) [UNM03429], Exhibit 6.12.
[559] [Dr. Administrator] Tr. at 149.
[560] UNM-Planned Parenthood of New Mexico, Inc., House Officer Affiliation Agreement (June 13, 2012), at 1, Exhibit 6.13; UNM-Planned Parenthood of the Rocky Mountains House Officer Affiliation Agreement (June 10, 2013), at 1, Exhibit 6.14.
[561] *See id.*; [Clinic A Dr. #1] Tr. 93-94, 167-69.
[562] *See* UNM staff rotations at Planned Parenthood, May 2016, Exhibit 6.15.

SWWO in 2014 and is a visiting instructor in the UNM Ob/Gyn department. [NM Doctor #5] is a clinical assistant professor in the Family Community Medicine department while being employed by SWWO.

Although as volunteers these SWWO physicians are not paid a salary by UNM, they do receive substantial benefits for their faculty status. For example, they receive "New Mexico Tort Claims Act professional liability insurance coverage provided to university employees" that is "extended to provide coverage for the duties and activities performed by the individual Volunteer Faculty members," provided that such activities were assigned to them by the department chairperson and that no other insurance covers such activities.[563] They also appear to have admitting privileges at the UNM Hospital.[564]

As volunteer faculty, these SWWO doctors also are entitled to a list of benefits at UNM that include the following:

> **HEALTH SCIENCES CENTER LIBRARY**—Access the HSC Library's online databases and extensive collection of over 600 full-text online journals check-out privileges; and educational classes
>
> **NEW MEXICO EDUCATORS FEDERAL CREDIT UNION**—membership
>
> **JOHNSON CENTER**—Facilities include the main and auxiliary gyms, handball courts, weight room, tennis courts and Olympic-size pool
>
> **ATHLETIC EVENTS**—50% discount on two season tickets for football, and men's or women's basketball games
>
> **POPEJOY CULTURAL SERIES**—discounts on event tickets
>
> **MUSEUMS**—Free admission to the Fine Arts Museum, Maxwell Museum of Anthropology, Geology Museums, Student Art Gallery, and Museum of Southwestern Biology
>
> **LIBRARIES**—Access to the Law Library on North Campus. The libraries on main campus include: Zimmerman Library, Fine Arts Center, Parish Library in the Graduate School of Management, Tireman Learning Materials Library in the Educational Complex and Centennial Science/Engineering Library

[563] Volunteer Faculty Professional Liability Insurance Extension of New Mexico Tort Claims Act [UNM03399], Exhibit 6.16.
[564] See [Clinic A Dr. #1] Tr. at 99-100.

UNIVERSITY PRESS—Publications may be purchased at a discount at UNM bookstores

GOLF—Reduced rates on quarterly/annual memberships for the 9-hole course. Discounts of the 18-hole Championship course may be available.

RECREATIONAL EQUIPMENT—Nominal fees to rent tents, camping gear, backpacks, snowshoes, cross-country skis, volleyball sets, etc.[565]

From documents obtained by the Panel, there is also a question whether benefits such as access to UNM library items are enjoyed by SWWO employees who are not known to be UNM faculty members, whether because they were directly provided such access by UNM or because a coworker at SWWO who is also a faculty member provided them such access from their accounts.[566]

Apart from involvement in the UNM fellowship at SWWO, UNM volunteer faculty members employed by SWWO are given *no teaching or other academic obligations* to UNM in exchange for the benefits provided by UNM. In fact, to the question "what duties did you have at UNM as a volunteer faculty member?" [Clinic A Dr. #1] answered, "No specific duties come to mind" and added she was "not . . . compelled to perform any teaching activities since becoming volunteer faculty."[567] Despite having admitting privileges, [Clinic A Dr. #1] has treated only one patient at UNM Hospital since her employment began at SWWO, and that instance occurred only because she happened to be speaking with candidates for the UNM Fellowship one day when, due to a staff shortage, her services were needed in order for an abortion to proceed.[568] UNM does, however, continue to receive on a regular basis one substantial benefit from SWWO: fetal tissue.

12. UNM Performs Research Using Tissue from Infants Aborted at SWWO and Shares the Tissue with Other Research Entities

Since 1995, SWWO has served as the only source of aborted infant tissue for research purposes at the University of New Mexico Health Sciences Center (UNMHSC). UNMHSC

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[565] UNM School of Medicine, Volunteer Faculty Benefits [SWWO001234-SWWO001235], Exhibit 6.17. *See also* [Clinic A Dr. #1] Tr. at 155, 259.

[566] *See, e.g.*, email correspondence of Feb. 16, 2016, in which [Clinic A Dr. #1], a UNM faculty member, provides an article to [NM Doctor #6], an SWWO employee not known to be on the UNM faculty, after the latter noted, "Once again, I'm having problems accessing the UNMHC [sic] library system." [SWWO001246], Exhibit 6.18.

[567] [Clinic A Dr. #1] Tr. at 155-56. *See also id.* at 258 ("I have no clinical or academic obligations necessarily attached to that faculty status"). When asked whether other SWWO doctors who doubled as UNM faculty members "ever taught courses at the University of New Mexico," [Clinic A Dr. #1] testified, "I can recall being told of maybe one." *Id.* at 158. When asked to identify any service she performed for UNM as a faculty member, she could think of only one example, when she "was asked once to participate in medical student oral examinations for their OB-GYN rotation." [Clinic A Dr. #1] Tr. 260-61.

[568] [Clinic A Dr. #1] Tr. at 101, 194-95.

asserts that "[t]he tissue is donated at no cost to UNMHSC and it is picked up at the clinic by UNMHSC staff."[569] According to UNM's Human Research Review Committee, "[w]omen undergoing elective termination of pregnancy are consented by Southwest Women's Options clinic, and can elect to have tissue used for research . . . . No interaction between women undergoing the procedure and [UNM] laboratory personnel occurs."[570]

Laboratory notes produced to the Panel reveal that a UNMHSC employee has collected aborted infant tissue from SWWO an average of 39 times a year since 2010.[571] Organs harvested include brain/head, heart, lung, eyes/retina, kidney, spleen, adrenal gland, intestines, bone marrow, and stomach. At least some infants were administered digoxin. By July 2015, however, digoxin was administered only to infants "20wks+."[572]

The notes contain information on aborted infants whose gestations ranged from approximately 11.5 to 30.5 weeks, with many in the 14- to 18-week range. At least 20 aborted infants were past 20 weeks gestation. The infants described include twins with "clubbed feet" aborted at 16 weeks gestation, a 22.5-week aborted infant with Down Syndrome, 20-week aborted twins with intact brains, a 25.3-week aborted female infant with an orofacial cleft, and a 30.5-week aborted "intact" infant.[573] The remains of these and hundreds of other aborted infants were collected from SWWO by UNMHSC staff and then taken to UNMHSC for use in research.

As recently as May 5, 2015, [NM Doctor #3] of SWWO wrote a letter to UNM detailing his desire to continue to provide aborted infant tissue for research: "This letter reconfirms my ongoing assistance and support for your research involving human fetal tissue. I have reviewed and been kept updated on your research and feel that the use of fetal tissue continues to be appropriate for your studies. Therefore, I will continue to facilitate your collection of samples from my clinic, following the usual inspection of the tissue."[574] The Panel has no information to suggest that SWWO has ceased providing aborted infant tissue to UNMHSC. The following chart illustrates the operation of the university/clinic model through the UNM-SWWO relationship:

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[569] UNM Second Submission to House Select Investigative Panel, at 1 (Feb. 16, 2016), Exhibit 6.19 [hereinafter UNM Second Submission]; UNM Document [UNM00560], Exhibit 6.20; UNM First Submission to House Select Investigative Panel, at 1 (Jan. 29, 2016), Exbibit 6.21; UNM Response to House Select Investigative Panel Subpoena, at 1 (Mar. 3, 2016), Exhibit 6.22; SWWO letter responding to document request, at 1 (Feb. 12, 2016), Appendix A, Exhibit 6.23.

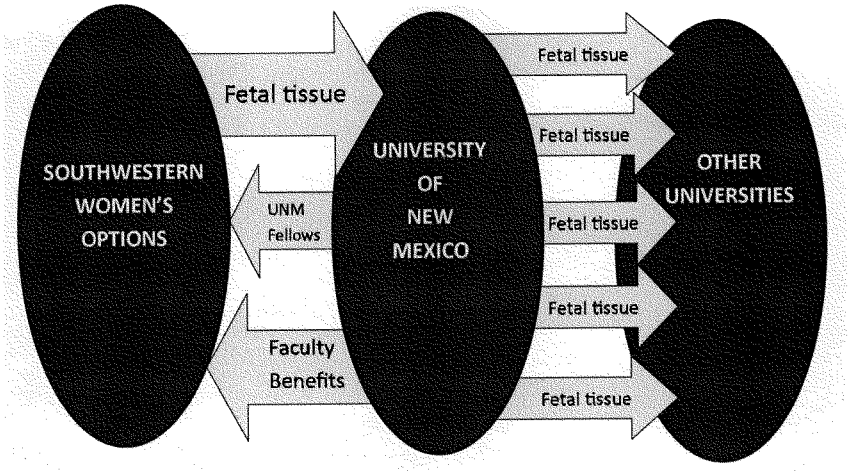
[570] UNM Study Document [UNM00790], Exhibit 6.24.

[571] *See* Procurement notes [UNM00004-UNM00052] (Approximation: 2010–43 days; 2011–25 days; 2012–45 days; 2013–49 days; 2014–41 days; 2015–33 days), Exhibit 6.25.

[572] *Id.* at [UNM00049], Exhibit 6.25.

[573] *Id.* at [UNM00019, UNM00041, UNM00024, UNM00006], Exhibit 6.25.

[574] Letter from [NM Doctor #3] to UNM [UNM01086] (May 5, 2015), Exhibit 6.26.



The tissue transferred from SWWO to UNM is of substantial value. According to UNM, "[s]ome of UNMHSC's most significant discoveries have arisen from its research involving fetal tissue."[575] The university stated that their collaboration with SWWO was integral to their research: "improved neonatal care and infant outcomes . . . . would not have occurred without the translational research efforts of the DREAM [Developmental Research, Education, and Mentoring Laboratory within UNM's Division of Neonatology] Lab in collaboration with [redacted] and the providers at Southwest Women's Options."[576]

In a July 22, 2015, letter to New Mexico legislators, [Dr. Administrator #2] described five studies using aborted infant tissue conducted or being conducted by a neonatologist in the Department of Pediatrics.[577] Additionally, [NM Research Doctor] of the DREAM Lab has published at least eight studies which used tissue from aborted infants.[578] Documents provided to

[575] UNM Second Submission, at 2, Exhibit 6.19.
[576] UNM Documents [UNM00560], Exhibit 6.20; UNM Documents [UNM00812 & UNM01105], Exhibit 6.27.
[577] Letter from [Dr. Administrator #2] to New Mexico legislators 3-4 (July 22, 2015), Exhibit 6.28.
[578] [NM Research Doctor] is an author or co-author of the following studies: (1) J Neonatal Perinatal Med. 2016 Mar. 12;9(1):91-7. doi: 10.3233/NPM-16915052. *Epsilon globin gene expression in developing human fetal tissues*; (2) Pediatr Res. 2015 Apr.;77(4):500-5. doi: 10.1038/pr.2015.15. Epub 2015 Jan 14. *VEGF mRNA and protein concentrations in the developing human eye* [hereinafter *Human Eye Study*]; (3) Circulation. 2014 May 27;129(21):2144-57. doi: 10.1161/CIRCULATIONAHA.114.009124. Epub 2014 Apr. 7. *Existence, functional impairment, and lung repair potential of endothelial colony-forming cells in oxygen-induced arrested alveolar growth*; (4) Gastroenterology. 2011 Jan.;140(1):242-53. doi: 10.1053/j.gastro.2010.09.043. Epub 2010 Sep 24. *TGF-β2 suppresses macrophage cytokine production and mucosal inflammatory responses in the developing intestine*; (5) Am J Physiol Gastrointest Liver Physiol. 2009 Jul.;297(1):G1-G10. doi: 10.1152/ajpgi.90730.2008. Epub 2009 May 14. *Epithelial cells in fetal intestine produce chemerin to recruit macrophages*; (6) Pediatr Res. 2008 Apr.;63(4):394-7. doi: 10.1203/PDR.0b013e318165b8d1. *Elevated erythropoietin mRNA and protein concentrations in the developing human Eye*; (7) Acta Paediatr Suppl. 2002;91(438):27-30. *Erythropoietin and hypoxia inducible*

the Panel list 18 studies conducted in collaboration with SWWO since 1995.[579]

The procurement notes provided to the Panel by UNM further confirm their acquisition of aborted infant tissue from SWWO for research purposes. References to specific studies were written in the notes along with lists of infant parts harvested. A lab technician wrote in May 2012 that someone from UNMHSC "asked clinic for digoxin treated tissue 24-28 wks. for methylation study + because [redacted] wants whole, fixed brains to dissect w/ summer camp students. Clinic est. 27 and 28 wks."[580]

While [NM Research Doctor] appears to have conducted most of the research using aborted infant tissue, UNM claims to have "identified eleven (11) medical students or residents and eight (8) faculty members who participated in fetal tissue research but who may not be named in published articles."[581] Further, documents produced to the Panel indicate that the Pediatrics and Neonatology departments sometimes partner with researchers from other departments as well.[582]

UNMHSC also shares tissue that it acquires with other researchers, including "[o]ne researcher . . . at the University of South Florida (previously worked at University of Alabama, Birmingham and University of Illinois, Chicago)," "the University of Ottawa in Canada (previously worked at University of Edmonton)," and "at the University of California San Francisco." UNMHSC maintains that "no consideration is exchanged for the tissue as part of these collaborative research projects."[583] UNM provided the Panel with emails between UNMHSC staff and researchers at other institutions. For instance, one UNM researcher wrote to a researcher in Edmonton, "We will try to get later gestation lung for you, sometimes we can get up to 20-22 weeks, but it is unusual these days to get non-digoxin exposed samples beyond 18 weeks (i.e., no living tissues)."[584]

UNMHSC represented to the Panel that it bears the cost for shipping tissue domestically while for transactions in Canada, the Canadian researcher provides a Federal Express account number.[585] After the Panel's chief counsel subsequently sent a letter to UNM requesting more complete records that would reflect other entities' transactions with UNM, budgets, IRB approvals, and late-term abortion activity at UNM, the university responded with a 60-page production, of which 35 pages are Federal Express and other courier records with names redacted and 21 pages are entirely redacted with no content visible at all.[586] This leaves the Panel

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factor-1 expression in the mid-trimester human fetus; (8) Pediatr Res. 1995 Jun.;37(6):806-11. *Neutrophil pool sizes and granulocyte colony-stimulating factor production in human mid-trimester fetuses.*

[579] UNM Documents [UNM00768-UNM00785, UNM00815-UNM00817 & UNM01059], Exhibit 6.29.

[580] Procurement notes [UNM00024], Exhibit 6.25.

[581] UNM Response to House Select Investigative Panel Subpoena 2 (Mar. 3, 2016), Exhibit 6.22.

[582] *See* Emails with the UNM College of Pharmacy Dept. of Pharmaceutical Sciences [UNM01071-UNM01075, UNM01078-UNM01083], Exhibit 6.30.

[583] UNM Second Submission, at 1, Exhibit 6.19.

[584] Email from UNM to University of Edmonton [UNM00910], Exhibit 6.31.

[585] UNM Second Submission, at 1, Exhibit 6.19.

[586] Letter from T. March Bell, Chief Counsel and Staff Director, House Select Investigative Panel, to UNM (Nov. 18, 2016), Exhibit 6.32; UNM Documents [UNM03457-UNM03516], Exhibit 6.33.

with an incomplete picture of UNM's monetary arrangements with other institutions and its IRB approval process, assuming one even exists.

In its responses to the Panel, SWWO has asserted that it "does not participate 'in research, study, or other work involving fetal tissue.'"[587] Evidence collected by the Panel, however, calls into question whether that statement is a misrepresentation by SWWO. In one letter UNM produced to the Panel, for example, [NM Research Doctor] wrote to [NM Doctor #3] that "we realized how valuable it would be to be able to match the individual patient's blood to the fetal tissue obtained. . . . we would need your help in matching the blood to the fetal tissue."[588] Another UNM document refers to the "translational research efforts of the DREAM Lab in collaboration with [NM Doctor #3] and the providers at Southwest Women's Options."[589] SWWO medical staff was even acknowledged in a published 2015 study on the developing human eye based upon eyeballs taken from fetuses aborted at SWWO. There the authors "thank[ed] [NM Doctor #3] and staff at Southwestern Women's Options . . . for technical assistance."[590] Thus, both internal and published documents suggest that the clinic and its personnel, especially [NM Doctor #3], did in fact participate in fetal tissue research beyond supplying the tissue to UNM.

13. UNM and SWWO's Failure to Properly Obtain Consent

From the Panel's investigation, it is apparent that there were several deficiencies in the consent process used to procure fetal tissue. Although both SWWO and UNM provided the Panel a consent form that purported to give patients notice that tissue from their pregnancies would be donated to UNM,[591] there is evidence that this form was not used. While [Clinic A Dr. #1] testified that SWWO's practice was to provide women an opportunity to donate the tissue that resulted from their abortions and to obtain their consent to do so, she admitted she had never gotten a consent from a patient at SWWO to make a fetal tissue donation—and did not even recognize the consent form that SWWO and UNM produced to the Panel.[592] She also admitted she was unaware of whether consent was required prior to the donation of fetal tissue.[593]

Further evidence supports the inference that patients were not regularly given a fetal tissue donation consent form at SWWO. [NM Patient], a woman who obtained an abortion from SWWO, has brought suit against the clinic and attested in an affidavit that she was never given a

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[587] Letter from SWWO to House Select Investigative Panel 1 (Nov. 30, 2016), Exhibit 6.34. SWWO purported to quote from the SWWO letter responding to document request (Feb. 12, 2016), at Appendix A, but this language does not appear in that document.
[588] UNM Document [UNM00562], Exhibit 6.35.
[589] UNM Document [UNM00812], Exhibit 6.27.
[590] *Human Eye Study* at 7.
[591] Client Information for Informed Consent, Donation of Fetal Tissue for Medical Research [SWWO000524], Exhibit 6.36. UNM produced the same form with Bates number UNM01103.
[592] [Clinic A Dr. #1] Tr. at 162-63, 165-67, 188-89, 212-13. The consent form itself was marked twice during [Clinic A Dr. #1]'s deposition, as Ex. 6 without a Bates number and as Ex. 12 with Bates number SWWO000524, the version the clinic produced to the Panel. *Id.* at 164-65, 212-13. [Clinic A Dr. #1] maintained it was the job of a counselor rather than a doctor to obtain a consent. *Id.* at 190.
[593] [Clinic A Dr. #1] Tr. at 273.

"consent to donate tissue that was separate from the consent for the [abortion] procedure."[594] Moreover, she alleges she was never informed by the doctors and staff at SWWO that her infant's remains were to be donated to UNM or another entity.[595] Neither, she alleged, was she informed of the nature and extent of any use of such remains, "which body parts were going to be used or donated," or what benefits could be expected from such use.[596] She added that she was not informed by SWWO doctors or staff that the doctor who treated her, [NM Doctor #5], and the director of SWWO, [NM Doctor #3], were volunteer faculty members at UNM, or that the clinic and the university had been collaborating on fetal tissue research since 1995.[597]

Even more problematically, the only semblance of consent SWWO allegedly sought from [NM Patient] for fetal tissue research was a phrase mentioning the use of "tissue and parts . . . in medical research" within a two-page consent form provided to her for the abortion procedure itself.[598] Thus, the only consent sought from her for fetal tissue donation came during what should have been a separate process of consent to the abortion procedure itself.

A letter from [NM Patient] to SWWO dated December 2, 2015, requested "all information regarding the disposal, donation or sale of any medical waste," but she allegedly never received any records regarding the disposition of her infant's remains.[599] Moreover, none of SWWO's or UNM's productions of documents to the Panel included the two-page consent form submitted to the Panel by [NM Patient] through her attorney. In September 2016, [NM Patient] read procurement notes dated October 17, 2012, that were attached to the Panel's referral of UNM and SWWO to the Attorney General of New Mexico that indicated brain tissue had been taken from one infant estimated at 11.5 weeks gestation and another at 12.7 weeks gestation.[600] Because [NM Patient]'s ultrasound taken on October 5, 2012, stated she was 12 weeks and two days pregnant, and because she obtained her abortion five days later on October 10—when staff informed her she was between 12 and 13 weeks pregnant—she believed her "baby was one of the two babies given to the University of New Mexico for their research."[601] This belief is consistent with SWWO's practice of storing fetal tissue in an on-site freezer until it is periodically picked up for transfer to UNM.[602] [NM Patient] attested, "If I had known my baby was going to be used for research I would have probably changed my mind about going through with the abortion," and added that the actions of SWWO and its doctors caused her "emotional

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[594] Affidavit of [NM Patient], Nov. 18, 2016 ([NM Patient] Aff.), ¶ 30, Exhibit 6.37. *See also* Complaint ¶ 47, [NM Patient] v. [NM Doctor #3], No. [redacted]-CV-[redacted] (N.M. Dis. Ct. Bernalillo County Nov. 30, 2016) ([NM Patient] Compl.), Exhibit 6.38. In an email dated Nov. 28, 2016, [NM Patient] gave permission to the Panel to disclose her identity publicly. Nonetheless, her name is not disclosed in the instant report.
[595] [NM Patient] Aff. ¶ 10; [NM Patient] Compl. ¶ 32.
[596] [NM Patient] Aff. ¶¶ 21-22, 26; [NM Patient] Compl. ¶¶ 35-38.
[597] [NM Patient] Aff. ¶¶ 15, 18-20; [NM Patient] Compl. ¶ 32.
[598] [NM Patient] Aff. ¶ 8 & Ex. A, at 1; [NM Patient] Compl. ¶¶ 11-12 & Ex. A.
[599] [NM Patient] Aff. ¶¶ 32-33 & Ex. B; [NM Patient] Compl. ¶¶ 54-57.
[600] Compare [NM Patient] Aff. ¶¶ 35-36 and Procurement notes, UNM00029, Exhibit 6.25. *See also* [NM Patient] Compl. ¶ 52.
[601] [NM Patient] Aff. ¶¶ 7, 12-13, 37-38; [NM Patient] Compl. ¶¶ 49-53.
[602] SWWO letter responding to document request (Feb. 12, 2016), at 5; [Clinic A Dr. #1] Tr. at 182-85. According to SWWO's Feb. 12 letter, pickup occurred weekly, but as noted above, procurement notes record that pickup occurred an average of 39 times per year since 2010, 45 times in 2012.

distress and mental anguish."[603] [NM Patient] additionally alleged that she was advised by staff that she could apply for Medicaid funding for her abortion procedure and that the paperwork supporting such funding was prepared by a doctor she never saw, [NM Doctor #6], and not her treating physician, [NM Doctor #5].[604]

14. The Panel's Criminal Referrals of UNM and SWWO

c) The June 2016 Referral

On June 23, 2016, the Panel sent a criminal referral of UNM and SWWO to the Attorney General of New Mexico that cited both state and federal law. New Mexico's Jonathan Spradling Revised Uniform Anatomical Gift Act (Spradling Act)[605] is based on the Uniform Anatomical Gift Act (UAGA),[606] which is adopted in some form in every state. The Spradling Act was enacted in 2007 to replace the State's existing Uniform Anatomical Gift Act[607] with provisions mirroring the UAGA.[608]

The Spradling Act, like the UAGA, includes stillborn infants and fetuses in the definition of "decedent" for purposes of obtaining consent from a relative before the deceased infant's body is donated for experimentation or transplantation. In the official notes to the UAGA, the drafters explain that the inclusion of stillborn babies and fetuses ensures that they "receive the statutory protections conferred by this [Act]; namely that their bodies or parts cannot be used for transplantation, therapy, research, or education without the same appropriate consents afforded other prospective donors."[609]

However, the notes also mention that states may choose to treat aborted fetuses differently, given the "complicated legal, scientific, moral, and ethical issues which may arise."[610] That is exactly what the State of New Mexico chose to do in 2007. In the Spradling Act, "'decedent' means a deceased individual whose body or part is or may be the source of an anatomical gift." It "includes a stillborn infant and . . . a fetus *but [does] not includ[e] a fetus that is the subject of an induced abortion*."[611]

Further, the Spradling Act provides that the Act "applies to an anatomical gift or amendment to, revocation of or refusal to make an anatomical gift, whenever made."[612] In other

[603] [NM Patient] Aff. ¶¶ 39, 42; [NM Patient] Compl. ¶¶ 60, 142.
[604] [NM Patient] Aff. ¶¶ 14-17; [NM Patient] Compl. ¶¶ 61-64, 110.
[605] N.M. Stat. Ann. § 24-6B-1, *et seq.*
[606] Revised Uniform Anatomical Gift Act (2006) (last revised or amended in 2009), National Conference of Commissioners on Uniform State Laws, http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf [hereinafter UAGA].
[607] N.M. Stat. Ann. § 24-6A-1 *et seq.*
[608] *See* Fiscal Impact Report, Revised Uniform Anatomical Gift Act (Mar. 14, 2007), at 3, https://www.nmlegis.gov/Sessions/07%20Regular/firs/HB1276.pdf.
[609] UAGA at 14.
[610] *Id.*
[611] N.M. Stat. Ann. § 24-6B-2 (emphasis added).
[612] N.M. Stat. Ann. § 24-6B-3.

words, all anatomical gifts in the State of New Mexico must comply with this act, and the bodies or body parts of aborted infants cannot be anatomical gifts.

SWWO's provision and UNM's acquisition of and research using aborted infant remains appears to violate the Spradling Act, which prohibits making an anatomical gift of the remains of any "fetus that is the subject of an induced abortion."[613] Even to the extent SWWO does use the fetal tissue donation consent form it produced to obtain consent from mothers of aborted infants, it still would not validate the donation of their infants' remains for research, because under the Spradling Act the bodies or parts of aborted infants may not be anatomical gifts.

UNM claims to have a "comprehensive Code of Ethical Conduct and compliance programs" in the area of "research involving tissue obtained from fetuses."[614] Further, the university maintains that "[o]versight for all research at UNMHSC is provided in the form of Institutional Review Boards, which ensure that all *federal* regulations and laws are followed regarding research studies" and that UNMHSC has "accreditation by the American Association of Human Research Participation."[615]

However, UNM's submissions to the Panel do not address compliance with the Spradling Act. Their efforts to conduct fetal tissue research in compliance with ethical standards and federal laws *do not* make UNM and SWWO less culpable for violating New Mexico state law. All anatomical gifts made in New Mexico must comply with the Spradling Act. Based on the information obtained and reviewed by the Panel, SWWO's provision of tissue from aborted infants, and the reception and use of the tissue by UNMHSC, arguably violates the Spradling Act.

Section 289g-2 is also implicated by the relationship between the two entities because of the value exchanged between them. As the clinic that provided abortions, SWWO incurred no extra expense in connection with the fetal tissue it transmitted to UNM, so there were no expenses to be reimbursed to SWWO. Indeed, the clinic might have been saved the expense it otherwise would have borne of disposing of the tissue that UNM received. While UNM may not have paid SWWO a sum of money it explicitly classified as consideration for the fetal tissue it received, UNM did provide SWWO a substantial value in the form of personnel offered to the clinic. The UNM Fellowship provided SWWO with medical personnel that expanded the volume of abortions it could provide without SWWO having to compensate them. UNM additionally conferred upon at least three staff physicians at SWWO faculty positions that gave them professional liability insurance coverage for UNM activities and access to numerous university facilities, in addition to numerous discounts. These faculty members in turn provided UNM no apparent benefit apart from the fetal tissue that came from SWWO, giving their relationship the components of an exchange of fetal tissue for valuable consideration. At a minimum, the intent and spirit of Section 289g-2 have been violated, and further investigation is necessary to determine whether criminal prosecution of SWWO or UNM should follow.

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[613] N.M. Stat. Ann. § 24-6B-2.
[614] UNM Second Submission, at 2, Exhibit 6.19.
[615] *Id.* (emphasis added).

d) The December 2016 Referrals

On December 21, 2016, after evidence of the failure of SWWO and UNM to provide informed consent were supplemented by the direct allegations of [NM Patient], the Panel sent another criminal referral to the Attorney General of New Mexico. If true, her allegation that the only informed consent to tissue donation sought from her was the cursory reference to the use of "tissue and parts . . . in medical research" in SWWO's abortion consent form amounts to violations of federal and state law by UNM and SWWO.

HHS regulations, which govern much of the human subject research conducted at UNM, requires in 45 C.F.R. § 46.116 a number of basic elements of informed consent:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
>
> (2) A description of any reasonably foreseeable risks or discomforts to the subject;
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
>
> (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
>
> (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
>
> (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
>
> (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
>
> (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is

> otherwise entitled.[616]

According to [NM Patient]'s allegations, both SWWO and UNM failed to provide any of these elements of informed consent, in violation of 45 C.F.R. § 46.116, accompanied by a violation of 45 C.F.R. § 46.117 for failing to present such consent in writing.

To the extent the research of the fetal tissue acquired by UNM related to transplantation for therapeutic purposes, any violations by SWWO and UNM would include violation of 42 U.S.C. § 289g-1(b)(1), which requires written consent from the woman acknowledging the nature of the research, the lack of "restriction regarding the identity of individuals who may be the recipients of transplantation of the tissue," and that the woman was not informed of any such recipients' identities. Moreover, the use of a consent form that simultaneously seeks consent for abortion and for fetal tissue donation under the alleged circumstances would appear to violate § 289g-1(b)(2)(A)(i), which requires the abortion consent to be "obtained prior to requesting or obtaining consent for a donation of the tissue . . . ."

UNM's own oversight policy provided as of 2015 that "appropriate informed consent by the mother" is required for "[t]he collection and storage of all fetal tissue for research."[617] The policy as revised April 11, 2016, further clarifies that UNMHSC

> will not acquire such fetal tissue from outside entities (a) without contractual and/or written assurance that the fetal tissue being acquired was collected in accordance with a process that separates the informed consent for the abortion procedure from the informed consent to donate such fetal tissue to the UNM HSC for Research, and (b) where there is contractual assurance that the terms of the acquisition complies fully with Section 112(a) of the NIH Act (42 U.S.C. § 289g-2(a)). In addition, the contractual assurance contemplated in Subsection 2 must indicate that there are no legal, ethical, or other restrictions against transferring the Research Tissues to the UNM HSC, nor against the UNM HSC's use of them.[618]

UNM did not produce this revised policy to the Panel.

Despite SWWO's inclusion of a fetal tissue donation consent form in its production, [NM Patient]'s allegation that it was never shown to her, combined with [Clinic A Dr. #1]'s admission that she did not even recognize the form and had never obtained consent to donate, raises a

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[616] 45 C.F.R. § 46.116(a). These elements are the minimum required, subject to exceptions for public benefit or service programs under § 46.116(c) and potentially additional requirements under § 46.116(b).

[617] UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP (Sept. 16, 2015) [UNM03420-UNM03428, at UNM03423], Exhibit 6.39.

[618] UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP 3 (Apr. 11, 2016), Exhibit 6.40. This revised policy additionally reinforces the Panel's June 23, 2016, referral regarding violation of the Spradling Act by requiring that fetal tissue for research be acquired "in accordance with the provisions of the" Spradling Act "and/or with contractual assurance that it was obtained in accordance with" that statute. *Id.* at 3-4.

serious question as to whether SWWO and UNM systematically violated the law, not to mention UNM's own internal policy, by conducting fetal tissue donations without more than the perfunctory reference to tissue research in SWWO's abortion consent form.

The same alleged deficiencies in the consent process at SWWO would constitute a violation of New Mexico's state law. Regardless of whether government funding or transplantation research is involved, N.M. Stat. Ann. § 24-9A-5, which is part of the Maternal, Fetal and Infant Experimentation Act, prohibits any "clinical research activity involving fetuses, live-born infants or pregnant women" unless the woman

> has been fully informed of the following:
>
> > (1) a fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental;
> > (2) a description of any attendant discomforts and risks reasonably to be expected;
> > (3) a description of any benefits reasonably to be expected;
> > (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
> > (5) an offer to answer any inquiries concerning the procedure; and
> > (6) an instruction that the person who gave the consent is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.[619]

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[619] N.M. Stat. Ann. § 24-9A-5(C). As discussed above, the Spradling Act prohibits use of fetal tissue resulting from induced abortion, but this informed consent provision provides a basis for liability separate from the underlying use of such tissue. It additionally should be noted that the Maternal, Fetal and Infant Experimentation Act defines the term "clinical research" as follows:

> "clinical research" means any biomedical or behavioral research involving human subjects, including the unborn, conducted according to a formal procedure. The term is to be construed liberally to embrace research concerning all physiological processes in human beings and includes research involving human in vitro fertilization, but shall not include diagnostic testing, treatment, therapy or related procedures conducted by formal protocols deemed necessary for the care of the particular patient upon whom such activity is performed and shall not include human in vitro fertilization performed to treat infertility; provided that this procedure shall include provisions to ensure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient, and no physician may stipulate that a woman must abort in the event the pregnancy should produce a child with a disability. Provided that emergency medical procedures necessary to preserve the life or health of the mother or the fetus shall not be considered to be clinical research . . . .

N.M. Stat. Ann. § 24-9A-1(D).

This statute is notably cited in the standard operating procedures of UNM's Office of the Institutional Review Board, but UNM failed to produce that document to the Panel.[620] Other sections of the Maternal, Fetal and Infant Experimentation Act make clear that neither a pregnant woman nor a fetus shall be involved as subjects in clinical research activity unless "the mother is legally competent and has given her informed consent,"[621] subject to penalties of imprisonment for less than one year and/or payment of a fine up to $1,000.[622]

C. The University of Washington and the Nation's Largest Fetal Tissue Bank

6. Summary

The Panel's investigation into the nation's largest fetal tissue bank at the University of Washington (UW) and outside abortion clinics provides another example of the interdependence of clinics and public research institutions. Over the last five years, over a dozen clinics have provided UW fetal tissue, and 40 universities or other public research institutions have been recipients of fetal tissue. UW claims that recipients of tissue are charged a flat fee of $200 regardless of the nature of the tissue researched and that the only payments it makes to clinics are to cover costs. The university failed to make a complete production, however. The Panel's independent research found that UW deploys doctors to outside abortion clinics and that numerous physicians on the staffs of those clinics hold faculty positions at UW. The invoices produced by UW are heavily redacted, rendering it impossible without more information to conduct a full forensic analysis under § 289g-2 of payments made to and by UW in connection with transfers of fetal tissue.

7. The University of Washington, in Conjunction with Numerous Clinics, Establishes the Nation's Largest Fetal Tissue Bank

UW offers an illustration of a university's relationship with numerous abortion clinics as sources of fetal tissue, with a substantial research operation funded by the federal government. The UW School of Medicine manages and operates the Birth Defects Research Laboratory (UW BDRL), which contains the largest fetal tissue bank in the nation. UW BDRL received over $600,000 from the NIH for FY 2015.[623] The Panel issued UW BDRL a subpoena dated April 29, 2016, to which UW responded with a partial production. The university claimed in response to six subpoena items it could not yet produce more "[d]ue to the breadth of the Subpoena," but that responsive documents would "be provided as soon as possible."[624]

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[620] *See* UNM Office of the Institutional Review Board, Standard Operating Procedures, effective Mar. 1, 2016, at 1-2, http://irb.unm.edu/sites/default/files/511.0%20Compliance%20with%20Applicable%20Laws%20and%20Regulations.pdf, Exhibit 6.41.

[621] N.M. Stat. Ann. §§ 24-9A-2(B), 24-9A-3(B).

[622] N.M. Stat. Ann. § 24-9A-6.

[623] NIH research portfolio, https://projectreporter.nih.gov/project_info_description.cfm?aid=8882485&icde=0, Exhibit 6.42.

[624] UW responses to subpoena, Exhibit 6.43.

The documents UW BDRL produced did not include any contracts with donors or recipients of fetal tissue, but it did provide a list of such donors and recipients. Over the previous five years, UW BDRL has procured fetal tissue resulting from abortion from a number of clinics and hospitals, including at various times the following (with an asterisk * noting fetal tissue sources identified by UW's IRB as current in 2016):

3. All Women's Health-North*
4. Cedar River Clinic-Renton*
5. Cedar River Clinic-Tacoma*
6. Cedar River Clinic-Yakima*
7. Evergreen Medical Center*
8. Planned Parenthood of Greater Washington and North Idaho (PPGWNI)*
9. Seattle Children's*
10. Seattle Medical and Wellness Clinic*
11. University of Washington Medical Center*
12. Allentown Women's Center
13. Group Health Cooperative
14. Harborview Medical Center
15. Swedish Medical Center—Edmonds[625]

UW BDRL also produced a list of 40 universities or other research institutions to which it has provided fetal tissue between 2010 and 2015:

1. Allen Institute for Brain Science
2. Cedars Sinai Medical Center
3. Children's Hospital of Philadelphia
4. Children's Mercy Hospital
5. Children's National Medical Center
6. Cold Spring Harbor Laboratory
7. Duke University
8. Fred Hutchinson Cancer Research Center
9. Harvard University
10. Indiana University
11. Johns Hopkins University
12. Lady Davis Institute
13. McGill University
14. Medical College of Georgia
15. New York State—Department of Health
16. NIH
17. Oregon State University
18. Pacific Northwest National Lab

[625] UW first production [000002-000008], Exhibit 6.44. Aurora Medical Services, sometimes listed as a source, was acquired by the Cedar River Clinics. Note that Pacific Northwest Facility and Seattle Reproductive Medicine are also sources of fetal tissue, but they only provide tissue from pregnancy losses, not elective abortions. *Id.* at [000008].

19. The Rockefeller University
20. Scripps Whittier Institute
21. Stanford University
22. Temple University
23. UCLA
24. UC Merced
25. UCSD
26. University College London
27. University of British Columbia
28. University of Kent—Canterbury
29. University of Michigan
30. University of Miami
31. University of Nebraska
32. University of North Texas
33. University of Pittsburgh
34. University of Puerto Rico
35. University of South Carolina
36. University of Washington
37. University of Wisconsin
38. US Environmental Protection Agency—Virginia
39. Washington University
40. Yale University[626]

8. The Sharing of Personnel Between UW and Outside Clinics That Supply Tissue

Through information available outside UW BDRL's production, the Panel has learned that, as in the case of UNM in Albuquerque, the university maintains a close relationship with area abortion clinics that includes the deployment of medical students to the clinics and faculty status for the clinics' staff physicians. Besides providing abortions directly through its family planning program, UW participates in the Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, which provides residents to outside abortion clinics.[627] Several faculty members perform abortions not only at UW's Medical Center, but also at outside clinics, several of which perform abortions at least well into the second trimester and raise questions about the standard of care for infants who survive the abortion procedure.

It is also noteworthy that a set of talking points produced to the Panel by the Allentown Women's Center designed to encourage women to give their consent to donate their infants' tissue misrepresents the necessity for fetal tissue research, including the following claims:

- Research that requires fetal tissue includes: Alzheimer's, Multiple sclerosis, Prostate and lung cancers, Diabetes, Spinal cord regeneration, Arthritis,

[626] UW first production [000010-000015], Exhibit 6.45.
[627] *See* The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Map and locations, http://www.ryanprogram.org/map-and-locations; Fellowship in Family Planning, Where are the Fellowships located?, http://www.familyplanningfellowship.org/fellowship-programs, Exhibit 6.46.

Parkinson's, Brain tumors, Neuropathy of HIV, Macular degeneration, Osteoarthritis, Sickle-cell anemia, Hepatitis and liver regeneration, Respiratory distress syndrome, and Blindness.

- You have already made a heart-wrenching decision. We know this is one more decision to make. Only fetal tissue and stem cells can further birth defects research. . . .

- Some tissue is already being used to help regenerate spinal cells so paralyzed people can walk someday.[628]

This grossly misrepresents the state of scientific research and available treatment. This report's discussion below of biomedical research includes a survey of how much clinical research utilizes fetal tissue.[629] Not only is fetal tissue unnecessary to study the conditions listed above; there are *no* current clinical trials being conducted using such tissue to research most of those conditions, with three exceptions—spinal cord injury, macular degeneration, and diabetes—in which cases less than 1% of the trials use fetal tissue.[630] Moreover, the same survey lists ten conditions arising during fetal life that affect infants and children, and there are currently no clinical trials for any of those conditions that use fetal tissue.[631] Further inquiry is necessary as to which personnel have made such claims in order to induce women to provide their consent and whether such misrepresentations are limited to one clinic or extend to UW and its other partners.

UW never produced documents sufficient to identify the doctors shared between the university and outside clinics.[632] Based upon other sources, the Panel learned of the following examples of the close ties between UW and area clinics that provide the university fetal tissue:

- The Cedar River Clinics: These clinics were co-founded by their executive director, [WA Clinic Director], in 1979 as the Feminist Women's Health Center. Its staff physicians include [WA Doctor #1], who had been medical director of Aurora Medical Services, a supplier of fetal tissue to UW, between 2000 and 2014. They are a major supplier of fetal tissue, with recipients that include

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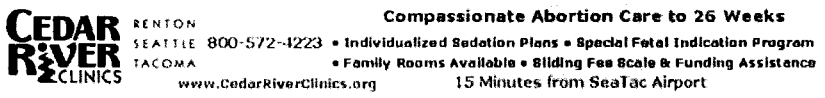
[628] Counseling suggestions for discussing tissue donation, Allentown Women's Center production, ALWC-001, Exhibit 6.47.
[629] *See* Chapter IX *infra*.
[630] *See* Chapter IX.C, table 1.
[631] *Id.* (diseases arising in the fetus and/or affecting children).
[632] That information should have been evident if a full production were made pursuant to UW BDRL's subpoena, including item 4: "Documents sufficient to reflect UW's organization chart, including information detailing UW personnel that procure(d) fetal tissue at the clinic level and the supervisory personnel for those proeurers of fetal tissue." UW produced only one chart listing six positions under the principal investigator at UW BDRL. UW first production, 000017, Exhibit 6.48. The Panel followed up on September 14 with various inquiries, including requests for a list of doctors "who have performed abortions at outside elinics while affiliated with UW" and a list of "doctors at outside abortion clinics who have faculty positions at UW." UW's second production, however, did not include information sufficient to inform the Panel on these points.

StemExpress and ABR.[633] The clinics perform late-term abortions—advertising their services up to 26 weeks:[634]



Among several lawsuits the clinics have faced was at least one medical malpractice suit arising from an abortion performed at 25+ weeks by [WA Doctor #2] that was alleged to have caused a woman excessive bleeding, threatening her life, and necessitated an emergency hysterectomy.[635] Several UW faculty members provide abortions at the Cedar River Clinics on at least a part-time basis, including [WA Doctor #3], associate professor of Ob/Gyn at UW and director of UW's Family Planning Division and the Family Planning Fellowship; [WA Doctor #4], acting assistant professor in UW's Ob/Gyn department; and [WA Doctor #1], clinical assistant professor at UW's Family Medicine Residency. Former Cedar River staff physician [WA Doctor #5] worked at the clinic while simultaneously working as an assistant clinical professor, "volunteer staff," between 1999 and 2010. Former Cedar River staff physicians [WA Doctor #6], who is now on the staff of the Swedish Medical Center, and [WA Doctor #7], currently with Northwest Women's Healthcare, were also UW residents.

- All Women's Health-North: [WA Doctor #8], owner and operator of All Women's Health-North, which is incorporated as ABBR Enterprises, and a clinic in Chicago also named All Women's Health, is a clinical instructor both at UW's Family Medicine Residency and Northwestern University's Feinberg School of Medicine. All Women's Health-North conducts abortion training for UW residents.[636] Although he is not known to be on UW faculty, [WA Doctor #9], the former medical director for the Cedar River Clinics, now performs abortions at All Women's Health-North. According to the former staff member at Germantown Reproductive Health Services interviewed confidentially by the Panel, [WA Doctor #9] told her he would push the gestational limit of abortions he performs as far as he could go.

- PPGWNI: [WA Doctor #10], who was medical director of PPGWNI for eight years, was trained as a UW resident and is a clinical associate professor at UW's

[633] *See* Chapter V *supra*.
[634] Abortion Clinics Online, Late Abortion Clinic, https://abortionclinics.com/clinic-category/late-abortion-clinic/.
[635] Investigative Report Prepared for the Medical Quality Assurance Commission, Exhibit 6.49; Complaint, [WA Patient] v. [WA Doctor #2] at 2-3, No. [redacted] (Wash. Super. Ct. King Co., June 25, 2010); telephone conference between Panel staff and plaintiff's attorney, Dec. 7, 2016. The case was ultimately referred to an arbitration panel and settled.
[636] Abortion in Washington blog, http://abortionstate.blogspot.com/2009/10/north-seattle-late-term-killing-field.html.

Central Washington Family Medicine Residency Program. PPGWNI doctor [WA Doctor #11] is also a clinical faculty member at UW.

9. Fetal Tissue Research at UW BDRL

UW BDRL conducts a substantial amount of fetal tissue research. [WA Research Doctor #1], a professor of pediatrics and author of numerous papers involving fetal tissue research, holds several titles at UW, including director of medical genetics at Seattle Children's and co-director of the Alaska Genetics & Birth Defects Clinic—programs that "provide virtually all of the pediatric genetic services for the states of Washington and Alaska," according to UW's website.[637] [WA Research Doctor #1] has been the author of UW BDRL's NIH grant proposals since at least 2005.[638] [WA Research Doctor #1]'s research includes a paper on optimal abortion techniques. Among other UW personnel who have authored or otherwise assisted fetal tissue studies[639] are [WA Doctor #3]; [WA Doctor #4]; [WA Research Doctor #2] of the pediatrics department's hindbrain malformation research program; [WA Research Doctor #3], a UW resident; and [WA Research Staff], technical operations manager at the medical school's WWAMI Institution for Simulation in Healthcare.

10. UW's Productions Were Insufficient for the Panel to Conduct a Full Analysis of UW's Fetal Tissue Transactions

UW BDRL claimed in its initial response to the subpoena that it "does not sell fetal tissue."[640] It added, however, that it "makes tissue available for research use by academic and non-profit research facilities. The recipient is invoiced a flat fee of $200. This fee is intended to cover UW's costs associated with the technical effort and related expenses in preparing the tissues that are not covered by the NIH grant."[641] Thus, UW BDRL did not represent that no money changes hands when tissue is received or donated, and it made no representation as to whether it purchased fetal tissue. The cover letter accompanying the partial production did admit that "the clinics or hospitals are reimbursed for costs associated with obtaining the fetal tissue for research."[642] Analysis under § 289g-2 requires clarification of the precise amounts that were expended as well as which costs were claimed for reimbursement since only certain costs may lawfully be reimbursed.

UW BDRL's initial production did not provide accounting records, invoices, other financial records, or communications that would have permitted the Panel to analyze and make

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[637] Excerpt from UW Division of Genetic Medicine, https://depts.washington.edu/genediv/directory/[WA Research Doctor #1], Exhibit 6.50.
[638] Grantome entries under [WA Research Doctor #1], http://grantome.com/search?q=@author%20%20[/[WA Research Doctor #1]], Exhibit 6.51.
[639] *See, e.g.*, [redacted] et al., "Effects of Digoxin and Delayed Dilation and Evacuation on Fetal Tissue Quality: Maximizing Opportunities for Research Participation," 92 Contraception 367 (2015).
[640] UW responses to subpoena item 2, Exhibit 6.43.
[641] UW responses to subpoena item 19, Exhibit 6.43.
[642] Letter from UW School of Medicine to Panel (May 10, 2016), at 1, Exhibit 6.52.

an independent assessment of the money that changed hands when fetal tissue was transferred.[643] This would be necessary to conduct a forensic analysis of UW's practices under § 289g-2, as would an examination of other value exchanged among various entities. The Washington attorney general, who is also responsible for representing the university, found without apparently conducting such analysis that PPGWNI had not received direct payment for fetal tissue from UW.[644] That office's inquiry apparently ended without an examination of an agreement between UW and one of the nine clinics that comprise PPGWNI. In emails exchanged between the AG's office and UW, UW representative [WA Administrator] told ADA Paige Dietrich he could send a business associate agreement and IRB authorization agreement between the entities, but after he asked whether they would remain confidential, Dietrich replied, "I don't think we'll need copies of the agreements."[645]

Months passed without UW BDRL following up on the production it represented in May would be made as soon as possible. In an effort to obtain expeditiously the information most critical to its investigation, on September 14, 2016, following several communications with UW's attorneys in the state attorney general's office, Panel staff distilled its pending subpoena categories to 14 specific inquiries to UW. In response, UW claimed that due to a temporary restraining order (TRO) issued August 3, 2016, by the United States District Court for the Western District of Washington blocking UW's release of records pursuant to a lawsuit filed under the Public Records Act, it was "unable to provide" records or other information responsive to 13 of the Panel's 14 inquiries.[646] While the TRO was broad enough to bind state and private parties, well established case law makes clear that any construction of the TRO that would prohibit compliance with a validly conducted congressional investigation would violate the Constitution. Chairman Blackburn accordingly sent a letter to the court citing such authority and requesting that the court make clear its TRO may not be construed to preclude UW's compliance with the Panel's subpoena.[647] The court issued a preliminary injunction dated November 13, 2016, that did not address Congress specifically, but narrowed the language of the TRO to permit disclosure while requiring redaction of personal identifying information.[648] While applicable law would not bind a party to make redactions in response to a congressional committee, the Panel, as a matter of accommodation, permitted UW to make such redactions, provided that the production would be accompanied by a redaction log disclosing any missing names. The log would be kept in a locked safe within the Panel's offices and accessed only if necessary to the investigation.

UW made its second production to the Panel on December 1, 2016. The vast majority of documents produced were various invoices, and they included extensive redactions without an accompanying redaction log. In addition to names, UW redacted identities of departments at the

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[643] *See* UW responses to subpoena items 5 ("communications . . . that direct or relate to a direction to UW personnel to procure fetal tissue"), 6 ("accounting records"), and 8 & 10 ("invoices" relating to fetal tissue), Exhibit 6.43.
[644] Memorandum from Deputy Attorney General and Senior Assistant Attorney General to Attorney General of Washington (Nov. 12, 2015), at 2, Exhibit 6.53.
[645] Emails (Sept. 17, 2015), Exhibit 6.54.
[646] UW second set of responses, Exhibit 6.55.
[647] Letter from Chairman Blackburn to Hon. James L. Robart, U.S. District Court for the Western District of Washington, Nov. 8, 2016, Exhibit 6.56.
[648] *Jane Does 1-10 v. University of Washington,* Case No. C16-1212JLR, Order Granting Motion for a Preliminary Injunction and Denying Motion to File a Supplemental Hearing, (W.D. Wash. Nov. 13, 2016), at 25.

university involved in various transactions, shipment dates, and even (in many but not all cases) descriptions of the tissue involved. To the extent discernible, the invoices reflect that UW charged $200 "per unit," $100 where the number of units involved was 0.5, and $300 where the number was 1.5, but it is unclear by what methodology these fractional units would be defined if in fact UW sets a flat fee schedule.[649] UW failed to produce communications involving UW personnel regarding fetal tissue and did not answer the Panel's questions regarding doctors who simultaneously work for the university and outside abortion clinics.

UW additionally produced 25 invoices for "clinic services" listing individual charges ranging from to $521 to $2,500. The invoices either do not specify what clinic services are involved or, when they apparently elaborate on the nature of such services, those elaborations are redacted—rendering it impossible for the Panel to conduct a forensic analysis of UW's financial arrangements with clinics.[650] UW's incomplete production raises more questions than it answers and demonstrates the need for further investigation.

D. Planned Parenthood Gulf Coast: A University Case Study

7. Summary

The Panel conducted an investigation of Planned Parenthood Gulf Coast (PPGC), a Planned Parenthood Federation of America (PPFA) affiliate that had its own research department. The Panel uncovered evidence that PPGC's research department may have violated 42 U.S.C. § 289g-2, Texas Penal Code § 48.02, and Tex. Penal Code Title 8 § 37.08.

c) Background on Planned Parenthood Gulf Coast

PPGC has a research department[651] that conducted studies for pharmaceutical companies,[652] the medical device industry,[653] and academic institutions, mostly in Texas.[654] PPGC bought its headquarters in 2010 largely because it met the needs of the research department.[655]

PPGC conducts in-house fetal tissue extraction, processing, storage, and shipping.[656] PPGC also ships tissue, but it requires the study sponsors to set up a FedEx account. PPGC prints the air bill, puts the air bill on the container, places the shipment on dry ice, and either has FedEx

[649] *See, e.g.*, Invoices for tissue collection and distribution, UW second production [000388, 000397, 000399, 000400, 000402, 000418, 000420, 000424, 000425, 000431, 000432, 000442, 000449, 000450, 000455, 000485, 000503, 000508, 000519, 000526, 000567, 000569, 000571, 000582, 000583, 000591, 000623, 000627, 000641, 000646, 000653, 000666, 000667, 000669, 000677, 000680, 000699, 000700, 000860], Exhibit 6.57.
[650] *See* Invoices for clinic services, UW second production [000941-000965], Exhibit 6.58.
[651] Center for Medical Progress, Transcript, Meeting with [PP Witness #2], [PPGC Abortion Services Official], [PPGC Staff], & Medical Assistant 4 (Apr. 9, 2015) [hereinafter CMP Meeting with PPGC personnel Tr.].
[652] *Id.* at 5.
[653] *Id.* at 6.
[654] *Id.* at 35.
[655] *Id.* at 96.
[656] *Id.* at 9, 14, 19-20, 29; 31, 40.

pick up the shipments or a PPGC staffer will drop it off.[657] PPGC bills customers for any sterile supplies needed for tissue procurement.[658]

From 2010 through 2012, PPGC procured placenta, blood, and fetal membranes for the University of Texas Medical Branch, Galveston (UTMB).[659] PPGC also unsuccessfully negotiated a contract to procure fetal tissue for the Baylor College of Medicine (BCM). PPGC ended its negotiations with BCM after the CMP videotapes were released. [PP Witness #2] told [BCM Staff] that the PPFA affiliate would not commit to contractual relations for the procurement of fetal tissue with any Texas academic institutions, unless those institutions spoke out about their need for fetal tissue.

The Panel has uncovered evidence that, despite those costs, PPGC may have made a profit from its procurement of fetal tissue. On a CMP videotape, [PP Witness #2] stated "this research department generates more revenue than the entire OB GYN research program at Baylor [College of] Medicine. . . . multiple, multiple times more revenue."[660]

d) History of Panel's Interactions with PPGC and Related Entities

During the course of its investigation, the Panel learned that PPGC procured fetal tissue for UTMB and BCM. On January 21, 2016, the Panel sent a document request letter to UTMB that asked for the production of a list of all entities from which it received or to which it donated fetal tissue, all communications related to the procurement of fetal tissue, all accounting records, and other materials.[661] During telephone conferences with UTMB officials, Panel staff agreed to narrow the scope of the request to include only communications, invoices and purchase orders.[662] UTMB produced the agreed upon documents on February 17, 2016.[663]

The Panel sent a document request letter to BCM that asked for the production of a list of all entities from which it received or to which it donated fetal tissue, all communications related to the procurement of fetal tissue, all accounting records, and other materials.[664] On February 9, 2016, BCM produced documents related to fetal tissue procurement from PPGC, letters it exchanged with the Texas Attorney General related to fetal tissue procurement, and documents

[657] *Id.* at 19-20.
[658] *Id.* at 90.
[659] Documents produced by the University of Texas Medical Branch to the Panel [UTMB 239], Exhibit 6.59.
[660] CMP Meeting with PPGC personnel Tr. at 90.
[661] Letter from Rep. Marsha Blackburn, Chairman, Select Investigative Panel on Infant Lives to President, University of Texas Medical Branch (Jan. 21, 2016).
[662] Telephone conference between Senior Public Affairs Officer, Department of Legal Affairs, University of Texas Medical Branch, and Panel staff (Feb. 2, 2016); Telephone conference between Senior Public Affairs Officer, Department of Legal Affairs, University of Texas Medical Branch, and Panel staff (Feb. 10, 2016).
[663] *See* Email from University of Texas Medical Branch official to Panel staff (Feb. 17, 2016).
[664] Letter from Rep. Marsha Blackburn, Chairman, Select Investigative Panel on Infant Lives to Dean, Baylor College of Medicine (Jan. 21, 2016).

specifically requested by the Panel staff.[665] BCM produced to the Panel the remaining responsive documents on February 24, 2016.[666]

8. PPFA Policy on Reimbursement for Fetal Tissue Donation Programs

c) April 2001 PPFA memorandum

On April 4, 2001, several PPFA officials sent a memorandum to affiliate chief executives, affiliate medical directors, and patient service directors, on federal regulations for participation in fetal tissue donation programs.[667] The memorandum notes that applicable federal laws "forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit 'reasonable payments associated with the transportation, implantation, processing, perseveration, quality control, or storage' of fetal tissue."[668]

The memorandum states that PPFA affiliates "can choose one of two methods to comply with these laws," as follows:

> One method would be to recover no costs associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.
>
> . . . The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred by the affiliate in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.
>
> Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a

[665] *See* Letter from Senior Vice-President and General Counsel, University of Texas Medical Branch, to Rep. Marsha Blackburn, Chairman, Select Investigative Panel on Infant Lives (Feb. 9, 2016).
[666] *See* Letter from Senior Vice President and General Counsel, University of Texas Medical Branch, to Rep. Marsha Blackburn, Chairman, Select Investigative Panel on Infant Lives (Feb. 21, 2016).
[667] Memorandum from [PPFA Lawyer], [PPFA Medical Officer #1], & [PPFA Medical Officer #2] to Affiliate Chief Executives, Affiliate Medical Directors, & Patient Service Directors (Apr. 4, 2001) [PPFA-HOU_E&C-000149-000150], Exhibit 6.60.
[668] *Id.*

> credible and good-faith computation of the actual cost of the space occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.[669]

The memorandum goes on to "remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well."[670]

[PP Witness #2] testified that she had seen the original. Despite that knowledge, the Panel has learned that the costs included in PPGC's contract and proposed contract with UTMB were based not on an independent auditor's credible and good-faith analysis of the actual costs it incurred to procure fetal tissue for UTMB. [PP Witness #2] testified that the costs "were basically back of the envelope type calculations" that she derived.[671] Rather it was based on back-of-the-envelope calculations by a single PPGC official. The fact that PPGC ignored the long-standing advice of PPFA's legal director when it drafted the UTMB contract and proposed amendment goes directly to PPGC's knowledge of the duty to comply with the applicable law and its willful decision to ignore the legal advice of its organization.

d) January 2011 redistribution of PPFA memo

The April 2001 memorandum was redistributed to PPFA affiliates in January 2011 under the signature of [PP Witness #1].[672] The memorandum sought

> . . . to remind affiliates about the federal law relating to payment for participation in such programs. The attached memo was sent almost exactly 10 years ago (yikes!). Given the time that has elapsed and that there has likely been staff turnover, we thought it would be helpful to resend it to assure continuing compliance with the statutes.[673]

Thus, PPFA affiliates, including PPGC, were twice put on notice about the steps they would have to undertake in order to participate in a fetal tissue donation program, and to ensure that any reimbursable costs they received did not constitute valuable consideration under the applicable federal and state laws.

9. PPGC Relationship with University of Texas Medical Branch

According to its production, from 2010 through 2012, PPGC procured "non-fetal tissues" from UTMB, which it admitted "included maternal tissues such as blood, placenta, and fetal

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[669] *Id.*
[670] *Id.*
[671] Transcribed Interview of [PP Witness #2] at 26 (Oct. 19, 2016).
[672] Memorandum from [PP Witness #1] to Affiliate CEOs, Medical Directors, & Patient Services Directors (Jan. 26. 2011) [PPFA-HOU_E&C-000148], Exhibit 6.61.
[673] *Id.*

membranes (i.e., amniotic sac)." PPGC continued, "No fetal tissues were acquired by UTMB from [PPGC] as part of these transactions."[674] During her transcribed interview, however, [PP Witness #2] testified that the UTMB study involved fetal tissue:

> The last research study that required the collection of first trimester fetal tissue was with the University of Texas Medical Branch. PPGC supplied pregnancy tissue for that study, which focused on a molecule called dystroglycan on placentas in an effort to prevent miscarriages. That research study ended in 2011.[675]

[PP Witness #2] testified that placenta is fetal tissue:

> [Q]: The placenta is a fetal or maternal organ; which is it?
>
> . . . A: It's a fetal organ, if I remember my training in nursing school correctly.[676]

PPGC personnel generally obtained consent from patients to donate fetal tissue. Emails produced by UTMB indicate that its personnel also obtained consent from patients and procured the fetal tissue.

a) PPGC Procures Fetal Tissue for UTMB

In September 2010, [UTMB Researcher # 1] sent an email to [PPGC Executive] that stated:

> So sorry for interrupting your Saturday. I generally am not one to go outside the chain of command, but I'm getting nowhere with this study that has been IRB approved since April. . . . It is essentially the same as the protocol we have been using for collection of chorionic villi, except that it calls for collection of one tube of blood at the time of IV start and also decidua at the time of CV collection. We provide all supplies, and my technician can do all the record-keeping,
>
> My previous study has been going well, and I don't think it has disrupted the flow of [the] clinic significantly. I have not received any invoice for the consents of 20 subjects, but the fee is negotiable.

[674] Documents produced by the University of Texas Medical Branch to the Panel [UTMB 239], Exhibit 6.59.
[675] Transcribed interview of [PP Witness #2] at 11 (Oct. 19, 2016).
[676] *Id.* at 83.

> We are hoping to establish and maintain a long-term relationship for collection of first and second trimester tissue for our studies . . . .[677]

[PP Witness #2] replied to [PPGC Executive]:

> If it's all the same to you, I'd prefer that you bounce the topic back to me knowing the following issues:
>
> 1. The study is not essentially the same. It now involves acquiring maternal blood, and the original contract is only for fetal tissue.
> 2. The original budget for the original study compensates PPGC only for the staff time obtaining informed consent. However the prep for sample collection entails sterile POC [Products Of Conception], and is more involved than prior tissue studies. SS actually brought this issue up with me. [PPGC Abortion Services Official] and I have had sporadic discussions about this, but haven't had time to formally discuss an appropriate budget. We are planning to meet this afternoon so I can bring a more realistic budget to [UTMB Reseacher # 1].
> 3. This study will require a separate contract and budget from the original study.[678]

UTMB did not produce to the Panel the original study or any related documents.

On October 1, 2010, [UTMB Researcher #1] wrote to [PP Witness #2] that "I deserve to know where we stand and what our potential timelines are."[679] [PP Witness #2] replied:

> We'll need to draw up a new contract, as the prior one was only for fetal tissue. We will only be able to enroll clients who get IV sedation into the study with the blood draw, otherwise it is not standard of care and the current ICF doesn't address the risk of a study-related blood draw.
>
> We need to renegotiate the budget for both studies based on feedback from SS. I met with SS mgmt last week and here is their proposal:
>
> $50 enrollment/consent process (consent per PPGC SOP, physician statements)

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[677] Email from [UTMB Researcher # 1] to [PPGC Executive], [UTMB 320-UTMB 325 at UTMB 324-UTMB 325] Exhibit 6.62.
[678] *Id.* at [UTMB 323].
[679] *Id.* at [UTMB 322].

> $100 room set up/collection (strip machines, sterile equipment, rinse hosing with sterile water, biologic sample collection)
>
> $50 enrollment/consenting fee if tech leaves without tissue (staff performed the work and tech didn't/couldn't stay to collect sample).
>
> $2000 annual admin fee (new or retraining staff, SS and Research Mgmt oversight, consent storage, supply storage).
>
> It would also be preferable if we amended the contracts to provision $Xamount/yr for a spend-down grant. PPGC is paid in advance for a set number of samples/yr, and then you collect at will . . . .
>
> Fee TBD – I was informed that you need help getting some of your supplies. I can check with our purchasing manager to see if we can do this, but I will need a list of supplies. The more detailed, the better such as manufacturer, product number, etc.
>
> Going forward I'll need to add these terms to the contract for the tissue-only study, and have both parties resign. I'll need to create a new contract for the blood&tissue study – we can copy and edit the original one to expedite the process. PPFA approval of the blood/tissue study will be expedited once we get this in order.[680]

[UTMB Researcher #1] replied, "That's fine . . . . [UTMB Researcher #2] will be the one to sign off and pay for his study that I'm collaborator on, and I will sign the new contract for my study. Can we split the $2000 admin fee between us? Or will it be faster just to list 'UTMB' and do the accounting on our end?"[681] On November 15, 2010, [PP Witness #2] sent an email to [UTMB Researcher #1] that stated, "I am waiting for CEO signature on the amended contract. I'll email you a copy once he's signed it."[682]

Invoices produced to the Panel by UTMB show that PPGC billed UTMB a total of $21,424.98 in annual administrative fees, consent payments, staff training, and supplies.[683] The Panel cannot determine whether those payments were made pursuant to first or the second contract.

On September 2, 2011, [PP Witness #2] sent an email to [UTMB Staff], the administrative assistant to [UTMB Researcher #2], who took over as the researcher on the

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[680] *Id.* at [UTMB 321-22].
[681] *Id.* at [UTMB 321].
[682] Email from [PP Witness #2] [UTMB Researcher # 1] (Nov. 17, 2010) [UTMB 326], Exhibit 6.63.
[683] Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch (Nov. 11, 2010,) [UTMB 328]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch (Nov. 11, 2010) [UTMB 329]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch (June 11, 2011) [UTMB 344]; Invoice from Planned Parenthood Gulf Coast to University of Texas Medical Branch (Sept. 29, 2011) [UTMB 252], Exhibit 6.64.

UTMB-PPGC project.[684] In her email, [PP Witness #2] stated, "Attached is the draft revised contract. Please review and return edits to me with tracked changes."[685] A version of the proposed contract, which was signed by [UTMB Researcher #2] but not by PPGC,[686] stated that PPGC "will consent up to 500 patients."[687] UTMB would have paid $150 per consent ($50 for "[s]taff time expense involving informed consent and relevant study documentation," plus $100 for "[s]terile procedure room set-up, sample preparation (strip machines, sterile equipment, rinse hosing with sterile water), biological specimen collections (ie blood, urine; non-fetal tissue) performed by staff").[688]

The draft contract stipulated:

> Per calendar year . . . Planned Parenthood is expected to obtain at least 25 executed informed consents at One Hundred Fifty Dollars ($150.00) each for a total of Seven Thousand Five Hundred Dollars ($3,750.00) [sic]. If within the course of the year the need arises for additional subject enrollment beyond 25, this number can be increased with mutual agreement by both parties, and an amendment to this agreement.
>
> [UTMB Researcher #2] will reimburse Planned Parenthood for actual number of fully executed informed consents, regardless of if a sample is obtained, at the rates above with the following payment schedule.
>
> > I. Annually in October, [UTMB Researcher #2] will pay Planned Parenthood 100% of the expected 25 executed informed consents.
>
> ii. Should the number of consents exceed 25, Planned Parenthood will invoice [UTMB Researcher #2] for these additional costs on a monthly basis. [UTMB Researcher #2] will pay Invoices within 30 days of receipt.
>
> iii. Failure to pay invoices will result in immediate halt to study enrollment.[689]

In addition to the fee for each executed informed consent, UTMB would have paid PPGC an annual administrative fee of $2,000, and $1,500 "for expenses related to staff time utilized in CITI Training as required by the UTMB Institutional Review Board. This reimbursement will be

[684] Transcribed interview of [PP Witness #2] at 63 (Oct. 19, 2016).
[685] Email from [PP Witness #2] to [UTMB Staff # 1] (Sept. 7, 2011) [UTMB 314], Exhibit 6.65.
[686] Tissue Supply and Biological Specimen Agreement, Amendment No. 2, between Planned Parenthood Gulf Coast, Inc. and [UTMB Researcher #2] of UTMB (July 26, 2011) [UTMB 299–UTMB 301], Exhibit 6.66.
[687] *Id.* at [UTMB 299].
[688] *Id.* at [UTMB 300].
[689] *Id.*

paid by [UTMB Researcher #2] upon receipt of certificates of training by Planned Parenthood Staff."[690]

The contract would have required [UTMB Researcher #2] to "provide all supplies necessary to conduct this study at Planned Parenthood. Supplies may be purchased by Planned Parenthood with the approval of the Director of Research and reimbursed by [UTMB Researcher #2] on a pass-through basis by [UTMB Researcher #2]."[691] The Panel notes that, had the July 2011 contract been executed as drafted, PPGC would have received $75,000 solely for the consent of patients.

10. PPGC's Relationship with Baylor College of Medicine

From November 1, 2013, through November 4, 2015, PPGC entered into negotiations to procure fetal tissue for BCM. On November 1, 2013, [PPGC Abortion Doctor] of PPGC sent an email to [BCM Researcher], a copy of which was sent to [PPGC Executive] and [PP Witness #2]. [PPGC Abortion Doctor] "putting" [BCM Researcher] "in touch with [PP Executive] "who oversees all research, as well as" [PP Witness #2] "who will be your primary contact person during the IRB approval/coordination phase."[692]

BCM personnel coordinated closely with the clinic, looking to [PP Witness #2] for direction. On March 24, 2014, [BCM Researcher] sent an email to [PP Witness #2]:

> Thank you for speaking with me today, and for your help with the IRB. Attached, please find my original submission. the consent form draft, and the response from the IRB. . . . Please feel free to contact me any time with any questions you may have[.][693]

On repeated occasions, including email correspondence on May 20 and June 3, 2014, [BCM Researcher] asked [PP Witness #2] for additional assistance by commenting on questions raised by BCM's IRB.[694]

Other emails evidence the close communication [BCM Researcher]'s staff had with [PP Witness #2]. In an October 20, 2014, email, [BCM Staff] thanked [PP Witness #2] "for the productive phone call." She continued, "I spoke with [BCM Researcher] after our phone call ended and she was really excited to know we had made so much progress. I have outlined some of her comments/feedback below . . . ."[695]

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[690] *Id.*
[691] *Id.* at [UTMB 301].
[692] Email from [PPGC Abortion Doctor] to [BCM Researcher] (Nov. 1, 2013), Exhibit 6.67.
[693] Email from [BCM Researcher] to [PP Witness #2] (Mar. 24, 2014), Exhibit 6.68.
[694] Email from [BCM Researcher] to [PP Witness #2] (May 20, 2014), Exhibit 6.69; Email from [BCM Researcher] to [PP Witness #2] (May 20, 2014), Exhibit 6.70.
[695] Email from [BCM Staff] to [PP Witness #2] (Oct. 20, 2014), Exhibit 6.71.

BCM produced to the Panel copies of a draft contract with PPGC for the procurement of fetal tissue that were never executed to the Panel.[696] The contract terms were similar to those proposed to UTMB: Under the proposed contract, BCM would have been required to pay PPGC $150 per executed informed consent, which included $50 for "staff time expense involved in obtaining consent and relevant study documentation" and $100 per-informed consent for sterile procedure room set-up and sample collection.[697] Under the contract, PPGC "will consent up to 500 patients."[698] The contract also called for BCM to reimburse PPGC annual administrative fees of $2,000 for "Surgical Services and Research Management oversight, consent storage, and supply storage. This list is not all inclusive."[699]

On November 17, 2014, [BCM Staff] sent [PP Witness #2] an email, the subject of which was "Pediatrics Research Proposal – BCM Researcher/Baylor College of Medicine – IRB Approval Obtained," that stated: "I would like to thank you for your support through our IRB review process. . . . Our IRB proposal for your outlining the study procedures/objectives is also attached for your reference."[700] [PP Witness #2] replied, "Thank you!"[701] Multiple email exchanges between [PP Witness #2] and BCM employees show that PPGC knew the BCM IRB had approved the proposal. For example: On June 22, 2015, [BCM Contract Manager] sent an email to [PP Witness #2] "to follow up on the status of the review for the MTA [Material Transfer Agreement] for [BCM Researcher] of Baylor College of Medicine."[702] On July 7, [PP Witness #2] replied suggesting modifications to the MTA, adding that "a contract specialist from BCM should edit it."[703]

On July 14, 2015, CMP began its release of videotapes obtained during the course of its 30-month long investigation into the sale of fetal tissue by PPFA affiliates to tissue procurement companies.[704] The release of the videos prompted several congressional investigations, and led to the Panel's creation by the U.S. House of Representatives. The timing behind the start of CMP's release of its videotapes is relevant in light of how PPGC ended its negotiations with BCM.

On October 13, 2015, [BCM Researcher #2] sent [PP Witness #2] an email in which she stated:

> . . . I hope you are well and had a great weekend.
>
> In light of recent events, do we need to make a change to our contract?

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[696] Tissue Supply and Biological Specimen Agreement between PPGC and BCM, Exhibit 6.72.
[697] *Id.* at ¶ 2(b)(i).
[698] *Id.* at ¶ 2(b)(i).
[699] *Id.* at ¶ 2(b)(iii).
[700] Email from [BCM Staff] to [PP Witness #2] (Nov. 17, 2014, 10:31 AM), Exhibit 6.73.
[701] Email from [PP Witness #2] to [BCM Staff] (Nov. 17, 2014, 12:01 PM), Exhibit 6.73.
[702] Email from [BCM Contract Manager] to [PP Witness #2] (June 22, 2015), Exhibit 6.74.
[703] Email from [PP Witness #2] to [BCM Contract Manager] (July 7, 2015), Exhibit 6.74.
[704] *See* Center for Medical Progress website, http://www.centerformedicalprogress.org/human-capital/.

> I still very much believe in the value of my NIH funded studies, and would very much like to proceed if that is possible.[705]

[PP Witness #2] responded in a November 4, 2015, email in which [PP Witness #2] stated that PPGC "will not commit to engage in any fetal tissue research endeavors at this time." [PP Witness #2] continued, "Academic institutions in Texas cannot remain publicly silent regarding their need for donated fetal tissue in research, yet have expectations that research collaboration with Planned Parenthood will remain intact."[706]

11. Potential Violations of Law

b) Applicable Laws

i) 42 U.S.C. § 289g-2

The applicable federal law on fetal tissue is § 289g-2, which is discussed above.[707]

ii) Texas Penal Code § 48.02

The Texas Penal Code makes it a misdemeanor if anyone "knowingly or intentionally offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers any human organ for valuable consideration."[708] Under the statute, "valuable consideration" does not include "a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services," "reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the organ;" or "reimbursement of expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ."[709]

The statute defines a human organ as "the human kidney, liver, heart, lung, pancreas, eye, bone, skin, fetal tissue, or any other human organ or tissue, but does not include hair or blood, blood components (including plasma), blood derivatives, or blood reagents."[710]

iii) Texas Penal Code § 37.08

Another provision of the Texas Penal Code makes it a misdemeanor for a person to lie to a law enforcement officer. The law states:

> A person commits an offense if, with intent to deceive, he knowingly makes a false statement that is material to a criminal investigation and makes the statement to: . . . a peace officer or

[705] Email from [BCM Researcher] to [PP Witness #2] (Oct. 13, 2015), Exhibit 6.75.
[706] Email from [PP Witness #2] to [BCM Staff] (Nov. 4, 2015), Exhibit 6.76.
[707] *See* Chapters I.C, II.B.3 *supra*.
[708] Tex. Penal Code § 48.02(b).
[709] Tex. Penal Code § 48.02(c).
[710] Tex. Penal Code § 48.02(a).

> federal special investigator conducting the investigation; or . . . any employee of a law enforcement agency that is authorized by the agency to conduct the investigation and that the actor knows is conducting the investigation.[711]

12. Findings

c) 42 U.S.C. § 289g-2 and Texas Penal Code § 48.02

The Panel's investigation raises questions of whether PPGC may have violated § 289g-2 and Texas Penal Code § 48.02. PPGC was paid for consent from patients. Consent is not a cost for which an entity can be reimbursed under § 289g-2. It is valuable consideration.

Documents produced to the Panel by UTMB show that PPGC also transferred fetal tissue to UTMB in exchange for valuable consideration as defined by the Texas Penal Code. Documents produced to the Panel by BCM show that PPGC knowingly offered to sell or transfer fetal tissue to BCM.

d) Texas Penal Code § 37.08

On October 22, 2015, nearly a year after PPGC learned that BCM's IRB had given its approval[712] and [PP Witness #2] sent her email to [BCM Researcher] in which she stated that PPGC would not commit to engage in any fetal tissue research endeavors at this time,[713] representatives of the Texas Department of Public Safety Texas Ranger Division, the House Police Department homicide division, and the Harris County district attorney's office visited PPGC headquarters to investigate allegations that PPGC may have violated Tex. Penal Code § 48.02.[714] (The report refers to PPGC as GCPP.)

During the course of this visit, PPGC's attorney introduced the law enforcement representatives to [PP Witness #2], who the attorney described as being a "Long time Baylor employee" who "had been instrumental in building the current research program."[715] The Texas Department of Public Safety Texas Ranger Division report stated that:

> [PPGC's attorney] advised that the last collected fetal tissue specimen collected by GCPP for a scientific study was on 07-26-2011, for the University of Texas Medical Branch. GCPP was recently approached by the Baylor College of Medicine and Rice

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[711] Tex. Penal Code Title 8, § 37.08.

[712] Email correspondence between [BCM Staff] & [PP Witness #2] (Nov. 17, 2014), Exhibit 6.73; Email correspondence between [BCM Contract Manager] & [PP Witness #2] (June 22 & July 7, 2015), Exhibit 6.74; Email from [BCM Researcher] to [PP Witness #2] (Oct. 13, 2015), Exhibit 6.75; Email from [PP Witness #2] to [BCM Staff] (Nov. 4, 2015), Exhibit 6.76.

[713] Email from [PP Witness #2] to [BCM Staff] (Nov. 4, 2015), Exhibit 6.76.

[714] Tex. Dept. of Pub. Safety Tex. Ranger Div., Report of Investigation Exhibit 6.77.

[715] *Id.*

> University for fetal tissue studies. The Institutional Review Board had not yet given approval for the Baylor or Rice studies.[716]

[PP Witness #2] and potentially other PPGC officials knew that BCM's IRB had approved the research project, despite representations of PPGC's attorney to Texas law enforcement officials that no IRB approval had been obtained by BCM.

C. The University of Minnesota

The practices of the University of Minnesota (UM) with respect to fetal tissue research and disposal were the subject of media and legislative inquiry that came to evoke skepticism of its institutional candor. Amid the heightened attention to questions surrounding fetal tissue trafficking in 2015, UM spokespeople initially denied to journalists and state legislators that fetal tissue research occurred on campus, but after a news outlet uncovered receipts of fetal tissue purchases, the university reversed course and admitted that such research had taken place.[717] Following a request it made under Minnesota's Open Records Law, the news outlet apparently had triggered the correction after it discovered that UM made payments for fetal tissue since between 2008 and 2014 from both tissue procurement companies and abortion clinics.[718]

After it was formed, the Panel followed with a request to UM dated January 21, 2016, for relevant documents dating back to 2010. UM responded with a production on February 29 that confirmed they had in fact procured fetal tissue from two procurement companies—Advanced Bioscience Resources (ABR) and StemExpress—the National Disease Research Interchange, and an abortion clinic, the Meadowbrook Women's Clinic of Minneapolis, which operates today under the banner of the Texas-based Whole Woman's Health Clinic.[719] This list may well be incomplete: UM's produced correspondence includes references to tissue orders from the university to Coriell Cell Repositories and the biotech company Regenx.[720] UM did identify ABR as its primary supplier of fetal tissue. Additionally, in stark contrast to its earlier denials of any fetal tissue research activity, UM disclosed that "approximately 10 researchers at the University of Minnesota" have used such tissue "currently or in the recent past" and that UM was the recipient of well over $1 million in NIH grants for projects that used fetal tissue.[721]

To the Panel's request for all accounting records related to the cost and pricing of fetal tissue, UM produced only invoices from ABR, which showed charges ranging from $275 to $2,675 that reflected ABR's varying fee schedule for different types of fetal tissue.[722] Thus, its

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[716] *Id.*

[717] *See* Letter from Marion O'Neill, Vice-Chair, House Higher Education Policy and Finance Committee, to University of Minnesota Board of Regents, at 1 (Oct. 22, 2015), Exhibit 6.78; Jeremy Olson, *After Awkward Flip-Flop, U Toughens Its Policies and Defends Practices*, Star Tribune, Jan. 31, 2016, at 1A; Youssef Rddad, *U Revisits Fetal Tissue Practices*, Minnesota Daily, Feb. 3, 2016, at 1.

[718] *See id.*

[719] UM letter responding to document request, at 1 (Feb. 29, 2016), Exhibit 6.79.

[720] UM production, Attachment A excerpts (Coriell & Regenx references), Exhibit 6.80.

[721] UM production, Attachment C, Exhibit 6.81.

[722] UM production, Attachment A excerpts (copies of ABR fees for services schedule), Exhibit 6.82; Attachment B (invoices), Exhibit 6.83.

practices with respect to fetal tissue raise questions of liability under § 289g-2 that have been examined in the above analysis of ABR and StemExpress.[723] Moreover, the monetary range of its tissue orders is apparently not reflected in the produced ABR invoices: the above referenced correspondence notes $3,555 of charges incurred by a UM lab manager on September 9, 2014, for tissue from Regenx.[724] UM did not disclose its payment practices or other exchanged value with respect to the area abortion clinic, a matter that merits further inquiry.

Independent of the question of what payments or other value exchanged implicate federal law, UM's underlying fetal tissue practices potentially violate several provisions of state law. Minnesota's Anatomical Gift Act permits the donation of fetal tissue only if it is "a stillborn infant or an embryo or fetus that has died of natural causes in utero."[725] Minnesota law also establishes as a "gross misdemeanor" the "use of a living human conceptus for any type of scientific, laboratory research or other experimentation except to protect the life or health of the conceptus, or" except for research "verifiable scientific evidence has shown to be harmless to the conceptus."[726] The state also requires fetal remains, whether "resulting from an abortion or miscarriage," to be disposed of "by cremation, interment by burial, or in a manner directed by the commissioner of health."[727]

UM apparently violated these laws by conducting research on aborted fetuses and additionally by disposing of fetal remains as biohazard waste. Following public disclosure of its practices, the university continues to procure fetal tissue, but it changed its policy to require such tissue to come from sources outside Minnesota and to provide for its disposal in the same way as donated human cadavers.[728] The institution's decision to cross state lines to procure fetal tissue appears to be an effort to avoid criminal liability under Minnesota law. This should prompt Congress to pass legislation that would prohibit the crossing of state lines to evade such basic protections of human dignity at the most vulnerable stages of life.

D. Colorado State University

Colorado State University (CSU) entered a contract with Planned Parenthood of the Rocky Mountains (PPRM) in March 2010.[729] Under the "Agreement for Transfer of Human Fetal Tissue" between PPRM and CSU, university personnel were permitted to collect tissue at the Planned Parenthood clinic. Planned Parenthood personnel were tasked with obtaining informed consent from patients, and the agreement specified that the university would "reimburse Planned Parenthood for reasonable expenses incurred during the tissue retrieval process such [as] the time involved in obtaining consent and packaging donations."[730]

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[723] *See* Chapter V *supra*.
[724] UM production, Attachment A excerpts (Regenx reference), Exhibit 6.80.
[725] Minn. Stat. § 525A.02 subdiv. 5.
[726] Minn. Stat. § 145.422 subdiv. 1 & 2.
[727] Minn. Stat. § 145.1621 subdiv. 3 & 4.
[728] *See* Jeremy Olson, *After Awkward Flip-Flop, U Toughens Its Policies and Defends Practices*, Star Tribune, Jan. 31, 2016, at 1A; Youssef Rddad, *U Revisits Fetal Tissue Practices*, Minnesota Daily, Feb. 3, 2016, at 1.
[729] *See* CSU and Planned Parenthood of the Rocky Mountains MTA, Exhibit 6.84.
[730] *Id.*

One invoice dated April 27, 2010, included a $1,500 charge to the university for "Administrative Start Up." Another invoice charged $1,600 for consent and processing for 10 specimens. These charges merit investigation given that, under their agreement, CSU provided the "packaging materials," and it is not apparent that there were any associated shipping costs.[731]

After public exposure of CSU's relationship with Planned Parenthood, a subsequent lawsuit against CSU claiming that CSU's contractual relationship with Planned Parenthood violated the state constitution,[732] and Congress' inquiry into the fetal tissue research industry, CSU halted acquisition of fetal tissue from any vendors implicated in the investigation.[733]

Like UM, CSU receives a significant amount in federal grants and obtains much of its fetal tissue from ABR and StemExpress. Between 2010 and 2015, CSU received seven NIH grants to support their projects using fetal tissue, at a taxpayer expense of $3.5 million.[734] During that same period, according to documents it produced to the Panel and in litigation, CSU paid ABR nearly $100,000[735] and paid StemExpress over $2,000 for fetal tissue.[736] As with UM, CSU's practices with respect to fetal tissue raise the same questions of liability under § 289g-2 that arise in the cases of ABR and StemExpress.

E. University of California at San Francisco

The University of California San Francisco (UCSF) has been characterized as "the hub of the abortion-rights countermovement in medicine."[737] The Fellowship in Family Planning began at the Bixby Center for Global Reproductive Health at UCSF—a two-year program following residency that pays doctors to "sharpen their skills in abortion and contraception, to venture into research and to do international work.[738] The program spread to around 30 other universities and presently has 246 graduated fellows.[739]

The Ryan Residency Training Program in Abortion and Contraception also began at the Bixby Center for Global Reproductive Health at UCSF in 1999. The Ryan Program "provide[s] resources and technical expertise to departments of obstetrics and gynecology to establish a formal, opt-out rotation in family planning, either by establishing or expanding an outpatient family planning service within the academic medical center or by linking institutions with a

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[731] *See* CSU documents [CSU000002, CSU000019-CSU000022], Exhibit 6.85.
[732] *See* First Amended Complaint, McIntire v. Board of Governors of the Colorado State University System d/b/a Colorado State University, No. 2015CV30865 (Dis. Ct. Larimer County Oct. 7, 2015) (McIntyre Am. Compl.).
[733] Rob White, *CSU halts some fetal tissue acquisition*, Coloradoan, July 28, 2015, http://www.coloradoan.com/story/news/2015/07/28/colorado-state-university-stem-express/30809431/.
[734] *See* NIH Research Portfolio Online Reporting Tools, https://projectreporter.nih.gov/reporter_searchresults.cfm.
[735] *See* McIntyre Am. Compl. at ¶ 42 & Ex. 4 (summarizing ABR invoices). This is consistent with documents CSU produced to the Panel.
[736] StemExpress documents, Exhibit 6.86.
[737] Emily Bazelon, *The New Abortion Providers*, N. Y. Times Mag., July 18, 2010, at MM30, http://www.nytimes.com/2010/07/18/magazine/18abortion-t.html?pagewanted=all&_r=0.
[738] *Id.*
[739] *See* Fellowship in Family Planning, Where are the Fellowships located?, http://www.familyplanningfellowship.org/fellowship-programs, Exhibit 6.46; Fellowship in Family Planning, Application information, http://www.familyplanningfellowship.org/application-information.

freestanding clinic, such as Planned Parenthood."[740] There are over 80 Ryan Program sites in the U.S. and Canada.[741]

Both the Fellowship in Family Planning and the Ryan Residency Training Program are funded by the Susan Thompson Buffett Foundation, which is heavily financed by Warren Buffett.[742]

UCSF is also involved in fetal tissue research. Between 2010 and 2015, UCSF received nearly $17.5 million in taxpayer funding from the National Institutes of Health for research projects using human fetal tissue.[743]

F. Washington University and Planned Parenthood of St. Louis

Planned Parenthood of the St. Louis Region and Southwest Missouri (PPSLR), reportedly the only clinic in Missouri that provides abortions, became the subject of a state legislative investigation in the wake of the revelations regarding Planned Parenthood in 2015. In one of the undercover CMP videos, [PP Witness #1] made a statement suggesting that the clinic was extensively involved in fetal tissue research when asked about tissue procurement opportunities: "[MO Doctor #1] is the Medical Director of the St. Louis region [of PP]. They do 2nd tri's they have a few extensive collaboration with all kinds of research, pretty dynamic medical director, his name is [MO Doctor #1]. I think that's definitely worth your while. And just looking at the map, if there was one place that was untapped, I would say St. Louis."[744]

On July 5, 2016, the Majority Caucus of the Missouri State Senate announced the initial results of their investigation into PPSLR. According to its report, the Senate was hindered in its investigation by "months of stonewalling by Planned Parenthood executives and also by top officials in Gov. Nixon's Department of Health and Senior Services," as well as the refusal of [MO Doctor #2], PPSLR's pathologist and the owner of Pathology Services, Inc., to testify, invoking his Fifth Amendment privilege against self-incrimination. The Senate did obtain enough information to assert that the clinic displayed "a shocking callousness towards vulnerable young women who seek their services" and employed procedures that "may very well constitute outright medical malpractice." The report concluded, "It appears that Planned Parenthood may very well have violated both state statute and Department of Health regulations in their [fetal] disposal practices."[745]

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[740] The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, About the Ryan Program, http://www.ryanprogram.org/node/1.
[741] The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Map and locations, http://www.ryanprogram.org/map-and-locations, Exhibit 6.46.
[742] *See* Emily Bazelon, *The New Abortion Providers*, N. Y. Times Mag., July 18, 2010, at MM30, http://www.nytimes.com/2010/07/18/magazine/18abortion-t.html?pagewanted=all&_r=0.
[743] *See* NIH Research Portfolio Online Reporting Tools, https://projectreporter.nih.gov/reporter_searchresults.cfm.
[744] Center for Medical Progress, Transcript of Videotape of Center for Medical Progress journalists and [PP Witness #1] (July 25, 2014), at 19.
[745] Missouri Senate Planned Parenthood Review Statement, at 1 (July 5, 2016), http://www.senate.mo.gov/16web/wp-content/uploads/2016/07/Missouri-Senate-Planned-Parenthood-Review-Statement.pdf.

The state senate investigation did not focus on the relationship between the clinic and Washington University of St. Louis, but the Majority Caucus' findings are relevant to analysis of that relationship. PPSLR's medical director, [MO Doctor #1], and four other physicians known to work at PPSLR have positions at the Ob/Gyn department of the Washington University School of Medicine:

- [MO Doctor #1] is an assistant professor.
- [MO Doctor #3] is an instructor.
- [MO Doctor #4] is a professor.
- [MO Doctor #5] is an associate professor in the division of family planning.
- [MO Doctor #6] is or was a clinical fellow.

Moreover, Washington University's medical school offers the Ryan Fellowship, by which university fellows are deployed to perform abortions at PPSLR.[746] The university has been acknowledged as a recipient of fetal tissue from UW, but the details of those acquisitions are unclear from UW's extensive redactions. That question merits further investigation, as do the questions of whether PPSLR supplies Washington University fetal tissue and, if so, whether monetary payments or other value is exchanged among the entities' shared personnel.

G. University of Wisconsin

The University of Wisconsin, School of Medicine and Public Health (UW SMPH) provides another example of a close relationship between a public research institution and Planned Parenthood—in this case, Planned Parenthood of Wisconsin (PPWI). The two entities have maintained a relationship in which UW SMPH would deploy faculty members of its Ob/Gyn department to work at a clinic designated by PPWI while still being paid by UW SMPH. The relationship was outlined in a memorandum of understanding obtained by the Panel and signed in 2008. It provided among other things that [WI Doctor #1], an assistant professor of Ob/Gyn at UW SMPH, would serve as the clinic's associate medical director.[747] The move was apparently part of a broader plan that included the procurement and transfer of fetal tissue for research, and UW SMPH admitted in response to a January 21, 2016, document request from the Panel that at the time, it obtained fetal tissue from PPWI.[748] [WI Doctor #1] was central to plans to provide late-term, second-trimester abortions in Madison, Wisconsin. When she departed Wisconsin for Harvard in 2010, a UW SMPH spokesperson made clear that this was "a change in who provides the service, but otherwise there is no change in our plans."[749] Both [WI Doctor #1] and another UW SMPH faculty member who also worked at PPWI, [WI Doctor #2], were

[746] Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Map and locations, http://www.ryanprogram.org/map-and-locations, Exhibit 6.46. The deployment of fellows to PPSLR was confirmed by a confidential witness and the following article: Abigail Golden, *The Medical Community's Hidden Abortion-Training War*, Daily Beast, Feb. 27, 2014, http://www.thedailybeast.com/articles/2014/02/27/the-medical-community-s-hidden-abortion-training-war.html.

[747] Memorandum of Understanding between the University of Wisconsin Madison and Planned Parenthood of Wisconsin, Inc. (Dec. 2008), Exhibit 6.87.

[748] Letter from UW SMPH to House Select Investigative Panel 3 (Feb. 15, 2016), Exhibit 6.88.

[749] Ryan J. Foley, *Doctor Key to UW Abortion Plan Leaving for Harvard*, Associated Press (June 14, 2010).

acknowledged "for their support with tissue collection and processing" in a 2014 article that had relied on the collection of 10 fetal brains at gestational ages of 10 to 18 weeks.[750]

[WI Doctor #2] remains active on both UW SMPH's Ob/Gyn faculty and PPWI, and she serves as director of the Ryan Fellowship at UW SMPH. The University of Wisconsin deploys residents to PPWI and memorializes this program in a separate contract between the University of Wisconsin Hospitals and Clinics Authority (UWHC) and PPWI.[751] As under the faculty contract, residents who participate in this program would be paid not by the clinic, but by the university via UWHC. Additionally, the contract provided that while at PPWI, residents would be supervised "by physicians who have UWSMPH faculty appointments and are members of the medical staff at PPWI, or, at the specific direction of the Director of Medical Education at PPWI," a position the contract also provided would be held by a UW SMPH doctor, "by other[]licensed PPWI physicians."[752]

While UW SMPH's relationship with PPWI continues, the school maintains that it has not obtained fetal tissue from that clinic network since November 2010. UW SMPH identifies the Albert Einstein College of Medicine, the University of Washington, and ABR as its sources of fetal tissue since 2010.[753] The vast majority of invoices it produced to the Panel come from ABR, dated between 2010 to 2015, and those range in amount from $310 to $2,200.[754] This is pursuant to ABR's high, tissue-specific fees for services schedule.[755] This range differs considerably from UW SMPH's charges from the University of Washington, which average under $300.[756] The transactions illustrate the problematical nature of ABR's practices under § 289g-2, which were examined above.[757] This is clearly material to any analysis of compliance by universities like UW SMPH.

H. University of Michigan

The University of Michigan (UMich) is a public research institution that conducts research using fetal tissue obtained from tissue procurement businesses and universities, though mostly from the former. In response to a January 21, 2016, document request from the Panel to the UMich Medical School, the university acknowledged eight research studies that utilized fetal tissue since 2010. Five researchers from different departments of UMich—psychiatry, urology, human genetics, environmental health sciences, and internal medicine—each procured fetal tissue for a separate research study.[758] Three more studies came from researchers in the

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[750] Prenatal Diagnosis 2014, 34, 431-437. Doi: 10.1002/pd.4322. *Differential Changes in Gene Expression in Human Brain During Late First Trimester and Early Second Trimester of Pregnancy*.
[751] Agreement for the Affiliation of Planned Parenthood of Wisconsin, Inc., with University of Wisconsin Hospitals and Clinics Authority for the Training of Residents (Apr. 14, 2009), Exhibit 6.89.
[752] *Id.* at 2.
[753] Letter from UW SMPH to House Select Investigative Panel 3 (Feb. 15, 2016), Exhibit 6.88.
[754] UW SMPH production [00052, 00069 (invoices for $310)] & [00012 (invoice for $2,200)], Exhibit 6.88.
[755] UW SMPH production [00002-00003], Exhibit 6.88.
[756] *See* UW SMPH production [00017-00018, 00027-00028, 00029-00030 (three charges of $200)] & [00023-00024, 00025-00026 (two charges of $400)], Exhibit 6.88.
[757] See Chapter V.D *supra*.
[758] Letter from UMich to House Select Investigative Panel 2-3 (Feb. 29, 2016), Exhibit 6.90.

department of ophthalmology.[759] ABR supplied the fetal tissue used in all three ophalmology studies and the internal medicine studies. Novogenix supplied tissue to internal medicine and human genetics. UW supplied tissue to the departments of urology and environmental health sciences, and the psychiatry department researcher obtained tissue from the UMich Health System.[760]

Physicians from UMich's Health System staff a Planned Parenthood clinic in Ann Arbor, Michigan, and medical students are eligible to provide abortions there through the Ryan Fellowship, in which UMich is a participant.[761] The Planned Parenthood clinic is even listed in the "our locations" section of the UMich Health System website.[762] Among the shared staff between UMich and Planned Parenthood, statements captured on undercover video by [MI Doctor] are of particular concern. [MI Doctor], who is both an associate professor in UMich's Ob/Gyn department and medical director for Planned Parenthood, told the following to a Center for Medical Progress journalist regarding her prospective involvement in the acquisition of fetal tissue for research:

> If I'm involved, it would have to go through my University of Michigan IRB, and they tend to be pretty easy about stuff and actually not require informed consent because that would be the biggest breach of confidentiality and of tissue discarded anyway, their feeling is you don't even need to consent people. Which is interesting. Planned Parenthood, on the other hand, does feel like you need to sign [unintelligible].[763]

This admission obviously raises serious questions about UMich's compliance with IRB and informed consent requirements.

In another part of their conversation, when [MI Doctor] was asked whether her past work in this area was "with a dedicated procurement organization," she replied, "No, it was with individual researchers who needed either decidual tissue or fetal, they were tr—fetal orbits, or, you know, specific, short-term research projects." While she had never encountered "a per-specimen fee" in such arrangements, she added that "all research projects . . . pay for the effort. . . . they've had sort of like grants to the agency to cover my time."[764] This statement is problematical because, if in fact she were paid for her time procuring fetal tissue, there arises the

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[759] *Id.*
[760] *Id.*
[761] *See* Michigan Outreach, Family Medicine Medical Consulting (Planned Parenthood), http://outreach.umich.edu/programs/family-medicine-medical-consulting-planned-parenthood/, Exhibit 6.91; The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Map and locations, http://www.ryanprogram.org/map-and-locations, Exhibit 6.46.
[762] Ann Arbor Planned Parenthood, http://www.uofmhealth.org/our-locations/ann-arbor-planned-parenthood, Exhibit 6.92.
[763] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNNF0991_20140408112137 (065000).
[764] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNNF0991_20140408115753 (009300-011300).

question of whether the grants she refers to cover more than statutorily permissible reimbursements for costs under § 289g-2. As for UMich institutionally, its use of ABR and Novogenix, both of which companies the Panel has discovered did charge per specimen, suggests the need for further inquiry into its fetal tissue acquisition practices.

VII. Case Studies of Late-Term Abortion Clinics

Chapter VII Redaction Key:

1. Abortion Doctor #1 is an abortion provider in Nebraska and Maryland.
2. Abortion Doctor #2 is an abortion provider in Colorado.
3. Abortion Doctor #3 is an abortion provider in Texas.
4. Dr. Administrator is a faculty member at the University of New Mexico.
5. Clinic A Dr. #1 is an employee of Southwestern Women's Options and a faculty member of the University of New Mexico.
6. Clinic B Staff #1 is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].
7. Clinic B Staff #2 is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].
8. Clinic B Staff #3 is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].
9. Clinic B Staff #4 is an employee of a late-term abortion clinic in Maryland for [Abortion Doctor #1].
10. Employee #1 is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].
11. Employee #2 is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].
12. Employee #3 is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].
13. Employee #4 is an employee of a late-term abortion clinic in Texas for [Abortion Doctor #3].
14. Patient #1 is a former patient of [Abortion Doctor #3].

A. Summary

Abortion clinics and hospitals typically use one of two methods when performing abortions in the second and third trimesters of pregnancy—dilatation and evacuation (D&E) or induction. Both of these procedures require a patient's cervix to be dilated over a period of hours to days prior to the actual procedure. During that dilation process, an infant can be delivered spontaneously.[765] If the infant has not been administered feticide—typically intracardiac potassium chloride injection (KCl) or intrafetal/intra-amniotic digoxin injection[766]— or if the feticide fails, infants are sometimes born alive.[767] While infants are not likely to be born alive during the D&E procedure, which entails dismembering and removing the infant and the placenta with forceps, infants have been born alive following the induction process in an induction abortion.[768]

The business practices and procedures of late-term clinics implicate numerous legal and ethical concerns. When human infants are born alive in late-term abortion clinics or hospitals, abortion providers are obligated to ensure that these infants are afforded all of the protections guaranteed by federal and state law. However, pressure from research institutions or procurement companies to provide human fetal organs and tissue at late gestations could negatively impact the treatment born-alive infants receive. Infants with congenital health problems are particularly vulnerable to neglect or abuse.

According to the Centers for Disease Control, between 2003 and 2014, 588 reported infant deaths included a code indicating that a cause of death was "termination of pregnancy, affecting fetus and newborn." At least 143 of these deaths could definitively be classified as involving an induced abortion; however, the CDC acknowledges that this could be an underestimate.[769]

A careful investigation of late-term abortion providers is necessary to ensure that entities are complying with the federal Born-Alive Infants Protection Act,[770] 42 U.S.C. § 289g, *et seq.*, federal regulations pertaining to human fetal tissue research, and state laws, including anatomical gift laws.

The significance of this inquiry includes the issue of the taxpayers' indirect support of late-term abortion. In fact, most of the doctors west of the Mississippi who openly perform third-trimester abortions have faculty positions at either the University of New Mexico or the

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[765] *See* SFP Clinical Guidelines: *Cervical preparation for second-trimester surgical abortion prior to 20 weeks' gestation*, Contraception 89 (2014) 75-84, http://www.contraceptionjournal.org/article/S0010-7824(13)00686-0/pdf.
[766] *See* SFP Clinical Guidelines: *Induction of fetal demise before abortion*, Contraception 81 (2010) 462-473, http://www.contraceptionjournal.org/article/S0010-7824(10)00019-3/pdf.
[767] *See* SFP Clinical Guidelines: *Labor induction abortion in the second trimester*, Contraception 84 (2011) 4-18, http://www.contraceptionjournal.org/article/S0010-7824(11)00057-6/pdf.
[768] *Id.*
[769] Centers for Disease Control and Prevention, Mortality Records with Mention of International Classification of Diseases-10 code P96.4 (Termination of Pregnancy): United States, 2003-2014, http://www.cdc.gov/nchs/health_policy/mortality-records-mentioning-termination-of-pregnancy.htm.
[770] 1 U.S.C. § 8.

University of Colorado. The broad public disapproval of such practices raises the question of why institutions that receive public funds should carry the tacit imprimatur imparted by institutional affiliation.

The Panel investigated several abortion providers and clinics around the country: [Abortion Doctor #1], [Abortion Doctor #2], [Abortion Doctor #3], University of New Mexico, and Southwestern Women's Options.

B. [Abortion Doctor #1]

1. Background on [Abortion Doctor #1]

[Abortion Doctor #1], M.D., performs abortions at two clinics—one in Nebraska, which he owns, and one in Maryland. [Abortion Doctor #1] began doing abortions full-time in 1988 in Nebraska.[771] [Abortion Doctor #1] has been very open about being an abortionist. He challenged the Partial-Birth Abortion Ban Act and lost before the United States Supreme Court in 2005. On his website, he shares that the *Washington Post*, Huffington Post, the *New York Times*, *Ms.* Magazine, and *Newsweek* have all featured him in their publications. Also, he was one of the late-term abortion doctors featured in the film *After Tiller*.[772]

In his Nebraska clinic, he offered late-term abortions, having worked with George Tiller for over 10 years, until Nebraska outlawed abortions after 20 weeks.[773] Because he could no longer provide abortions after 20 weeks in Nebraska, he began performing late-term abortions in a clinic in Maryland, thus splitting his week between the two clinics.

2. The Panel Issues a Subpoena to [Abortion Doctor #1]

On May 15, 2016, the Panel sent [Abortion Doctor #1] a subpoena, inquiring into whether his abortion clinics, specifically the clinic in Maryland, have participated in fetal tissue donation, what abortion procedures are conducted in the clinics, and the clinics' protocols in the event an infant is born alive following an abortion procedure.

[Abortion Doctor #1] partially complied with the subpoena by producing information from his clinic in Nebraska. He stated that he has not donated any fetal tissue at the clinic in Nebraska.[774] However, he did not produce any information for the Maryland clinic, claiming he did not have the authority to do so since he is not an agent of the facility.[775]

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[771] *About [Abortion Doctor #1]*, http://www.abortionclinics.org.
[772] *Id.*
[773] *Id.*
[774] Letter from Pillsbury Winthrop Shaw Pittman LLP, to Rep. Marsha Blackburn, Chairman, House Select Investigative Panel 3 (May 23, 2016), Exhibit 7.1.
[775] *Id.* at 4.

3. The Panel's Investigation into the Clinic in Maryland

Therefore, the Panel decided to interview several of the employees of the clinic in Maryland in order to investigate the above-mentioned items. In the interviews, when questioned on when [Abortion Doctor #1] thinks viability occurs, the employees stated 27 weeks.[776] [Clinic Worker #1] stated that up to 27 weeks, the woman does not need to provide a justification for the abortion, as shown in the following excerpt from the transcript:

> Q Can I just, the 20- to 27-week range, which is about 50 percent of your practice, so do the women have to provide any justification for the abortion during that period of time from 20 to 27 weeks?
>
> A No, ma'am.
>
> Q So it's only after 27 weeks?
>
> A Correct.[777]

In a video filmed undercover by the Center for Medical Progress (CMP) at the National Abortion Federation (NAF) conference, [Clinic Worker #1] said that they do not do many abortions before 18 weeks. She said, "We're one of the big three. We do up to 35 weeks."[778] According to an affidavit written by a confidential informant who has been a sidewalk counselor (*i.e.*, an individual who prays outside the clinic and tries to dissuade women from having abortions) outside the clinic for 5 years, "many of the 3rd-trimester abortions are elective."[779] She goes on to say that since [Abortion Doctor #1] has been working in Maryland, "we have recorded over 40 such post-viability abortions being done for trivial reasons having nothing to do with the health or life of either mother or baby."[780]

In addition to the concerns that purely elective, post-viability abortions are taking place, there have been several medical complications that have occurred at the clinic, under the watch of [Abortion Doctor #1]. Since December 2010, 9 women have been transferred to a nearby hospital due to complications from an abortion at this clinic, with 7 of them being emergency transports.[781] The most alarming factor is that 5 of the 9 transfers have occurred since December 2015. In April 2016, the Panel met with a confidential informant, a former employee of the clinic, who claimed that [Abortion Doctor #1] is not fit to practice due to arthritis in his hands.

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[776] Transcribed interview of [Clinic Workers #1, #2, #3, and #4] (July 21, 2106) at 37, 139.
[777] *Id.* at 38.
[778] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNPB0298_20150419143440.
[779] Affidavit of [Confidential Informant], Dec. 3, 2016 ([Confidential Informant] Aff.), ¶ 3, Exhibit 7.2.
[780] [Confidential Informant] Aff., ¶ 4, Exhibit 7.2.
[781] Transcribed interview of [Clinic Workers #1, #2, #3, and #4] (July 21, 2106) at 32.

Recently, [Abortion Doctor #1] did not practice at the Maryland clinic for 8 weeks. Rumor spread that he had stopped his practice in Maryland. However, he returned to the clinic on December 11, 2016, and resumed providing abortions.[782]

C. [Abortion Doctor #2]

1. Background on [Abortion Doctor #2]

[Abortion Doctor #2], M.D., M.P.H., Ph.D., owner of the Boulder Abortion Clinic, has been an abortionist since 1973.[783] He wrote *Abortion Practice*, a medical textbook on abortion.[784] He also was featured in the movie *After Tiller*, in which he spoke openly about his practice.

In 2003, [Abortion Doctor #2] wrote a paper titled "Has the Human Species Become a Cancer on the Planet?: A Theoretical View of Population Growth as a Sign of Pathology." In the paper, he discusses how population growth is one of the greatest problems we face today.[785] Throughout the paper, he analogizes human population growth on the planet with cancer in the body—rapidly growing and damaging.[786] He concludes with stating that the world must decide to lower the number of births or it will occur "because of ecological limitations and resource degradation with the result of an increased number of deaths or declining fertility through social disorganization (warfare)."[787] He states that the debates over abortion make the problem worse because it limits options to couples who wish to decrease their fertility, and he praises the United States' decision to help countries around the world with their family planning programs.[788]

In 2003, after the passage of the Partial-Birth Abortion Ban Act, [Abortion Doctor #2] wrote an article for *Slate* in which he states that the Partial-Birth Abortion Ban is ambiguous and that his patients are afraid the law will prevent them from getting abortions in the future. He finishes the article by describing an abortion he had recently done on a woman who was 17 weeks pregnant:

> I ruptured the membranes and released the fluid to reduce the risk of amniotic fluid embolism. Then I inserted my forceps into the uterus and applied them to the head of the fetus, which was still alive, since fetal injection is not done at that stage of pregnancy. I closed the forceps, crushing the skull of the fetus, and withdrew the forceps. The fetus, now dead, slid out more or less intact.[789]

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[782] *The Return of [Abortion Doctor #1] to Germantown*, Pray for Germantown (Dec. 11, 2016), http://www.prayforgermantown.com.
[783] *About [Abortion Doctor #2]*, Boulder Abortion Clinic, P.C. (2010) http://www.drhern.com.
[784] *Id.*
[785] [Abortion Doctor #2], *Has the Human Species Become a Cancer on the Planet?: A Theoretical View of Population Growth as a Sign of Pathology*, 36 Current World Leaders, 1089, at 1.
[786] *Id.* at 17.
[787] *Id.* at 18.
[788] *Id.* at 18.
[789] [Abortion Doctor #2], "Did I Violate the Partial-Birth Abortion Ban?," Slate (Oct. 22, 2003) http://www.slate.com/articles/health_and_science/medical_examiner/2003/10/did_i_violate_the_partialbirth_abortion_ban.html.

He finished the article by stating, "Did I do a 'partial-birth' abortion? Will John Ashcroft prosecute me? Stay tuned."[790]

2. The Panel's Investigation into [Abortion Doctor #2]

On November 2, 2016, the Panel sent [Abortion Doctor #2] a document request letter, inquiring into whether his abortion clinic has participated in fetal tissue donation, what abortion procedures are conducted in the clinic, and the clinic protocols for if an infant is born alive following an abortion procedure. Shortly after the Panel sent the letter to [Abortion Doctor #2], he bought a full-page ad in the *Denver Post* in which he published the letter from Chairman Blackburn and his response to the letter. The Panel had not disclosed to the public that it had sent a letter to [Abortion Doctor #2]. In his letter, he writes, "[Y]our letter to me and letters to other physicians constitute a program of target identification for anti-abortion assassins. . . .Your 'investigation' is legislative harassment that endangers our lives. The blood of any of us who are assassinated is on your hands."[791]

[Abortion Doctor #2]'s accusation carries no weight due to the fact that he himself made it public that the Panel sent him a document request. The Panel kept this information confidential. It did not issue a press release. The public would not have known about this letter if [Abortion Doctor #2] had not told them through the publication of his letter in the *Denver Post*. He then, after exposing his own name, asked the public for money to cover security costs for his clinic through a fundraising website, an unnecessary measure if he had kept his involvement with the investigation confidential, as the Panel had done for him.[792] Furthermore, [Abortion Doctor #2] has always been open and public about his abortion practice, through his clinic's website, his advertisements, his outspoken articles, and his participation as a star of the film *After Tiller*.

In [Abortion Doctor #2]'s response to the Panel, he concludes by citing the Fifth Amendment as his reason for not complying with the document request.

D. [Abortion Doctor #3]

1. Summary

Over the course of its investigation, the Panel collected statements and video from former employees and a patient of [Abortion Doctor #3] who have alleged numerous violations of law at one or more of his clinics, describing the practitioner as conducting himself with depraved indifference to infant life and committing acts of murder. [Abortion Doctor #3] was previously referred to the District Attorney of Harris County, but the investigation into the matter was

[790] *Id.*

[791] Letter from [Abortion Doctor #2] M.D., M.P.H., Ph.D. to Rep. Marsha Blackburn, Chairman, House Select Investigative Panel 4 (Nov. 16, 2016), Exhibit 7.3.

[792] [Abortion Doctor #2], *Boulder Abortion Clinic Renovation and Security Upgrades*, crowdrise, https://www.crowdrise.com/boulder-abortion-clinic-renovations-and-security-upgrades. As of December 13, 2016, [Abortion Doctor #2] had earned $53,325 on the fundraising website.

deficient. After [Abortion Doctor #3]'s attorney agreed to forward a document request from the Panel to his client, the Panel made such a request for documents due November 16, 2016, but received no response to the request. Due to the gravity of the allegations against him, the Panel made a criminal referral forthwith to both the United States Attorney General and the Texas Attorney General on December 7, 2016. The allegations of violations of both federal and state law are recounted below.

2. Allegations Against [Abortion Doctor #3]

[Abortion Doctor #3] is an abortion provider who has operated at three locations in Houston, Texas and one in Dallas. Several former employees who worked with him at one or more of the Houston locations have come forward alleging numerous violations of law.

According to several of his employees, including [Employee #1] and [Employee #2], who were medical assistants, and [Employee #3], who assisted with administrative tasks, numerous patients of [Abortion Doctor #3] delivered infants alive prior to their demise, which the doctor himself brought about. Specifically, [Employee #1], who assisted the doctor in the operating room at the Aaron Women's Clinic (Aaron), estimated that "[d]uring a typical week with a full patient load, . . . [Abortion Doctor #3] would perform abortions at 20 or more weeks gestation, *i.e.*, later in the second trimester or in the third trimester, on approximately 40 patients."[793] Of that number, [Employee #1] asserted:

> approximately three or four infants would show signs of life. This typically happened when infants were extracted from the cervix in a breech position. At times, the infant would slide completely out because of the extent of the dilation caused by the laminaria administered to patients. In all such cases, [Abortion Doctor #3] would terminate their lives. The signs of life they exhibited would include movement of the stomach as the infant breathed or movement of the toes or fingers.[794]

[Abortion Doctor #3] would terminate the lives of these infants, [Employee #1] further alleged based on those incidents she witnessed, by any of several methods, including the following:

> snipping the infant's spinal cord with scissors; cutting the neck with Sopher forceps or similar instruments; twisting the infant's head; using forceps, other instruments, or his finger to crush the "soft spot" of the infant's head, or crushing it by the same means through its stomach; or inserting his finger down its throat. If the infant's cranium was coming out first, he would usually use his index finger

[793] Affidavit of [Employee #1], Dec. 5, 2016 ([Employee #1] Aff.), ¶¶ 1-2, Exhibit 7.4. [Warning: Graphic Content]
[794] *Id.* ¶ 3.

> to puncture its head, but if it was coming out feet first, he would instead insert an instrument in the back of the infant's head.[795]

Several of the same allegations were also made by [Employee #2].[796]

[Employee #3] was not in the treatment rooms when abortions took place, but she alleges she learned from her coworkers of numerous infants whose lives were terminated by [Abortion Doctor #3] after showing signs of life following partial or full extraction from the uterus.[797] On one occasion, she stated that she learned from a coworker of an infant killed by the doctor after surviving an abortion; as he was preparing to put it into a bag for disposal, she maintained, the infant had "opened up his eyes and grabbed his hand."[798]

[Employee #1] stated that "[o]f the three to four infants terminated in a typical week by [Abortion Doctor #3] while showing signs of life, on average, approximately one or two would be put to death after they had left the birth canal entirely. The balance were terminated while they were partially out of the birth canal."[799] [Employee #1] added that she never observed [Abortion Doctor #3] "make an attempt to keep alive or resuscitate any infant who showed any signs of life or to direct anyone else to do so," an observation consistent with [Employee #3]'s understanding.[800]

[Employee #1] also alleged that "[Abortion Doctor #3] performed numerous abortions during the third trimester in cases that did not involve any serious threats to the mother's or the infant's health."[801] [Employee #2] asserted, "As long as the patients had the cash, he was going to do it past the 25 weeks."[802] Four photographs identified by [Employee #1] and [Employee #3] as taken in the sterilization room of one of [Abortion Doctor #3]'s clinics, the Women's Pavilion, in 2012 depict the remains of infants clearly in their third trimester when they were allegedly terminated by [Abortion Doctor #3].[803] According to [Employee #1], the tears in the neck line visible in the photos are "inconsistent with" terminations done "while the infant[s were] entirely inside the uterus."[804] Thus, besides being late-term abortions, they were likely either partial-birth abortions or homicides committed after full delivery.

[Employee #1] and two other employees at the clinic, [Employee #3] and [Employee #4], additionally alleged that the doctor regularly falsified sonogram results to misrepresent the

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[795] *Id.* ¶ 4.
[796] *See* Redacted video—see key. [hereinafter Redacted video] ("Sometimes he would go through the stomach as well. . . . He would like force it [the instrument] through the stomach . . . and he twists it.") ("he would put, like, his finger . . . through the throat") (statements of [Employee #2]).
[797] Affidavit of [Employee #3], Dec. 6, 2016 ([Employee #3] Aff.), ¶ 2, Exhibit 7.5. [Warning: Graphic Content]
[798] Redacted video.
[799] [Employee #1] Aff. ¶ 5.
[800] *Id.* ¶ 5; [Employee #3] Aff. ¶ 2.
[801] [Employee #1] Aff. ¶ 6.
[802] Redacted video.
[803] [Employee #1] Aff. ¶ 6; [Employee #3] Aff. ¶ 3. According to [Employee #3], the photos were taken July 26, 2012. *Id.*
[804] [Employee #1] Aff. ¶ 6.

gestational age of the fetus. Some sonograms, they maintained, would be falsified to "overstate the gestational age of the fetus in order to overbill customers."[805]

In other cases, according to [Employee #1] and [Employee #3], "sonograms would be falsified to conceal the advanced gestational age of the fetus beyond the legal limit in Texas."[806] [Employee #1] claimed:

> I have witnessed this happen in cases involving fetuses as old as 28 weeks. [Abortion Doctor #3] would typically tell his ultrasound technician in cases involving fetuses beyond a certain gestational age to allow him to perform the ultrasound himself; he would then bring the patient an ultrasound picture showing another fetus at the gestational age he was misrepresenting to the patient.[807]

An affidavit from a patient attached hereto alleges another specific case of manipulation: [Patient #1], a woman who obtained an abortion in 2002 at "24 to 25 weeks" gestation, "worried that I was too far along. The girl doing my ultrasound told me that 'ultrasounds can be manipulated.' The clinic determined me to be 23 weeks."[808] "On two occasions that I witnessed," [Employee #1] also alleged that "[Abortion Doctor #3] failed to inform a patient she was pregnant with twins."[809]

According to [Employee #1] and [Employee #3], the doctor "would regularly make use of pre-drawn medicine," including Demerol and Nubain, "without properly logging or storing it." They added:

> This included improperly storing medicine in a food refrigerator. On one occasion, [Abortion Doctor #3] concealed these practices during an inspection from the Harris County Public Health office by having a nurse put pre-drawn medicine in basins, which she hid in the trunk of her car while the inspector was present."[810]

[Employee #1] and [Employee #3] also allege the doctor failed to keep a registered nurse on site in the recovery room at Aaron, which "left unqualified workers to draw and administer drugs."[811] [Employee #1] added that [Abortion Doctor #3] concealed this deficiency from authorities by "hir[ing] a nurse from a temp agency for a few days at a time when a government inspection was

[805] *Id.* ¶ 7; [Employee #3] Aff. ¶ 4; Statement of [Employee #4], Nov. 23, 2012, at 1, Exhibit 7.6.
[806] [Employee #1] Aff. ¶ 7; [Employee #3] Aff. ¶ 4.
[807] [Employee #1] Aff. ¶ 7.
[808] Affidavit of [Patient #1], June 17, 2013, Exhibit 7.7.
[809] [Employee #1] Aff. ¶ 8.
[810] *Id.* ¶ 9; [Employee #3] Aff. ¶ 5. *See also* Redacted video.
[811] [Employee #1] Aff. ¶ 10; [Employee #3] Aff. ¶ 6.

scheduled."[812] [Employee #1] recorded examples of storage, recordkeeping, and personnel violations in an undercover video she took in 2011.[813]

Additionally, according to [Employee #1]:

> [Abortion Doctor #3] would regularly fail to observe proper sterilization procedures. This included the doctor's habitual reuse of a bottle of Betadine, which is used for cleaning prior to the procedure, that was not cleaned or stored, and which he handled with his gloved hand for patient after patient when going inside the cervix. Additionally, after removing instruments such as Hawkins-Ambler's dilators and Bierer and Sopher forceps from sterile packages, he would place unused instruments back in the sterile package to use on other patients. He often would do so wearing gloves that he did not change between seeing one patient and another, or between trips to the restroom. . . . Instruments in [Abortion Doctor #3]'s clinic were not regularly soaked in sterilizing solutions as they needed to be for specified periods of time in order to be sterile. The exception to this occurred prior to government inspections. The vast majority of the doctor's assistants in the sterilization room were uninformed on proper methods of sterilization. In order to reduce his costs, [Abortion Doctor #3] also habitually disposed of biohazardous waste in standard garbage bags instead of sterile bags required for such waste.[814]

The same failure with respect to sterilization was also alleged by [Employee #2], [Employee #3], and [Employee #4].[815]

3. Violations of Applicable Laws

Federal law makes clear that infants that are born, regardless of whether naturally or by extraction during an abortion, are entitled to the same protections given to every other person. Under the Born-Alive Infants Protection Act of 2002, "every infant member of the species homo sapiens who is born alive at any stage of development" is considered a person.[816] This is so whenever an infant undergoes "complete expulsion or extraction from his or her mother" and "has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or

[812] [Employee #1] Aff. ¶ 10. For additional information regarding the deficiencies in [Abortion Doctor #3]'s nursing staff and other allegations regarding possible violations at his clinics, see Statement of [Employee #1] in support of Complaint against [Abortion Doctor #3], D.O., Apr. 26, 2010, Exhibit 7.8.
[813] Clinic in Texas video by [Employee #1].
[814] [Employee #1] Aff. ¶¶ 11-12. See also Statement of [Employee #1] in support of Complaint against [Abortion Doctor #3], D.O., Apr. 26, 2010, at 3.
[815] Redacted video; Statement of [Employee #4], Nov. 23, 2012, at 1.
[816] 1 U.S.C. § 8(a).

extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion."[817]

The Partial-Birth Abortion Ban Act of 2003 makes clear that such protections apply even if the infant is only partially extracted from the mother's body at the time its life is ended. Specifically, a prohibited "partial-birth abortion" occurs when a person knowingly commits "an overt act . . . that kills the partially delivered living fetus" after the fetus is partially delivered with its entire head "outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel."[818] The only exceptions occur when such a procedure "is necessary to save the life of a mother whose life is endangered" by certain categories of physical conditions.[819] Violations of the 2003 act are punishable by fines, imprisonment for up to two years, or both.[820]

The foregoing allegations advance numerous federal violations against [Abortion Doctor #3]—of the Partial-Birth Abortion Ban Act in those cases involving his terminations of partially delivered infants and of the Born-Alive Infants Protection Act in those cases where the infants have completely exited a mother's body. In at least the latter cases, they also amount to allegations that [Abortion Doctor #3] violated Texas' criminal homicide statutes. First, the allegations constitute murder, defined by the Texas Penal Code as "intentionally or knowingly caus[ing] the death of an individual."[821] Second, the allegations against [Abortion Doctor #3] constitute capital murder under Texas law in both of the following circumstances, either one of which is sufficient to establish that offense:

- "the person murders more than one person . . . during different criminal transactions but the murders are committed pursuant to the same scheme or course of conduct;"[822] and

- "the person murders an individual under 10 years of age . . . ."[823]

The murders alleged against [Abortion Doctor #3] occurred on a repeated basis, and all occurred pursuant to his course of conduct as a provider of abortion who was alleged to have systematically killed any infant aborted while showing signs of life. The second circumstance is independently established by the obvious fact that every alleged victim was under 10 years of age.

[Abortion Doctor #3]'s alleged conduct would also violate the gestational age limit established under Texas law. Former employees of the doctor allege he performed abortions as late as the third trimester.[824] Third trimester abortions are prohibited with narrow exceptions, inapplicable according to the allegations in the instant case, where "the abortion is necessary to

[817] 1 U.S.C. § 8(b).
[818] 18 U.S.C. § 1531(b)(1).
[819] 18 U.S.C. § 1531(a).
[820] *Id.*
[821] Tex. Penal Code § 19.02(b)(1).
[822] Tex. Penal Code § 19.03(a)(7).
[823] Tex. Penal Code § 19.03(a)(8).
[824] [Employee #1] Aff. ¶ 6; [Employee #3] Aff. ¶ 2.

prevent the death of the woman," the "unborn child has a severe, irreversible brain impairment; or . . . the woman is diagnosed with a significant likelihood of suffering imminent severe, irreversible brain damage or . . . paralysis."[825] Since H.B. 2 became effective October 29, 2013, abortions additionally have been prohibited when "the probable post-fertilization age of the unborn child is 20 or more weeks."[826] [Abortion Doctor #3]'s abortion practice is believed to continue to the present day, so it merits investigation whether he has violated both gestational limits.

The allegations that [Abortion Doctor #3] regularly falsified sonogram results to misrepresent the gestational age of the fetus in order to overbill also potentially implicate both state and federal law. Regardless of whether the patient or another entity is responsible for payment, Texas law clearly prohibits fraudulent billing. Such conduct would constitute a form of theft[827] in addition to violating Texas' prohibition on insurance fraud.[828] In those cases in which patients were eligible for Medicaid coverage, such allegations would implicate numerous federal criminal prohibitions on false statements to federal agencies[829] and on false statements involving health care benefit programs,[830] as well as the prohibitions on health care fraud.[831] Such conduct would also violate the federal False Claims Act[832] and Texas' prohibition of Medicaid fraud.[833]

Other provisions of Texas law prohibit additional conduct alleged above on the part of [Abortion Doctor #3], including the following:

- Misrepresentation of sonogram readings: In addition to violating the above-cited statutes prohibiting fraud, tampering and altering records containing patient data is prohibited under 25 Tex. Admin. Code § 135.9(d).

- Failure to properly store and log medication: The obligation to maintain and provide drugs safely and to properly log their use is set forth in detail under 22 Tex. Admin. Code

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[825] Tex. Occ. Code § 164.052(a)(18). The Texas Health and Safety Code contains an additional prohibition of third-trimester abortions, under which such abortions are permitted only when they are "necessary to prevent the death or a substantial risk of serious impairment to the physical or mental health of the woman" or "the fetus has a severe and irreversible abnormality," in which case the physician is required to submit a written certification of the applicable conditions to the Department of State Health Services. Tex. Health & Safety Code §§ 170.002(b)-(c).

[826] Tex. Health & Safety Code §§ 171.044, 171.045. Exceptions apply when abortion is deemed necessary "to avert the woman's death or a serious risk of substantial and irreversible physical impairment of a major bodily function, other than a psychological condition." Tex. Health & Safety Code § 171.046. Note that these provisions of H.B. 2 were not challenged in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016).

[827] Tex. Penal Code § 31.03.

[828] Tex. Penal Code § 35.02.

[829] 18 U.S.C. § 1001; 18 U.S.C. § 287. An accompanying prohibition on conspiracy in connection with such claims is established by 18 U.S.C. § 286.

[830] 18 U.S.C. § 1035.

[831] 18 U.S.C. § 1347; 42 U.S.C. § 1320a-7b(a). If fraud is proven to have been carried out by utilizing either the mails or other applicable interstate carriers or communications, the federal mail and wire fraud statutes would also be implicated. *See* 18 U.S.C. §§ 1341, 1343.

[832] 31 U.S.C. § 3729(a)(1).

[833] Tex. Penal Code § 35A.02.

§ 291.76 and made applicable to ambulatory surgical centers under 25 Tex. Admin. Code § 135.12.

- Lack of adequate medical staff: 25 Tex. Admin. Code § 135.7 requires health care practitioners to meet numerous requirements that include necessary and appropriate training and to adhere to state law and "the standards and ethics of their professions." 25 Tex. Admin. Code § 135.15 specifies requirements for an organized nursing service under the direction of a qualified registered nurse and other personnel that must be present at the medical facility. [Abortion Doctor #3]'s former employees allege a violation of these sections. Additional investigation is warranted into whether clinic practices were in compliance with other requirements for adequate medical staff, including 25 Tex. Admin. Code § 135.10, which addresses additional facility requirements, and 25 Tex. Admin. Code § 135.11, which addresses anesthesia and surgical services.

- Failure to observe proper sterilization procedures and disposal practices: 25 Tex. Admin. Code § 135.11(b)(12) requires the development, implementation, and enforcement of such procedures, and 25 Tex. Admin. Code § 135.52(d)(14) requires sterilizing facilities to be included and properly maintained and utilized.

- Fraudulent concealment from government authorities of the foregoing alleged violations: The fabrication, alteration, and in applicable cases concealment involved in these allegations entail conduct proscribed by Tex. Penal Code § 37.09. It also subverts the state's right to inspect facilities containing controlled substances pursuant to Tex. Health & Safety Code § 481.181.

E. University of New Mexico and Southwestern Women's Options

As noted above, Albuquerque, New Mexico, is one of the known providers of late-term abortions. SWWO openly performs a large quantity of abortions into the third trimester, and UNM Hospital will provide abortions beyond 25 weeks where there is "a maternal indication or a fetal indication."[834] Yet neither UNM nor SWWO appears to have any apparatus or procedure to ensure the survival of infants who show signs of life following extraction from the uterus. This is evident from [Dr. Administrator]'s deposition testimony when she was questioned on this subject:

> Q . . . I'm trying to understand if any of the doctors that were on the fellows program that . . . went to Southwestern Women's Options, or any of the doctors from the University of New Mexico that were on a fill-in rotation at Planned Parenthood, or any of the doctors at the University of New Mexico reproductive health center, or any of the doctors at the University Hospital ever told you,

[834] [Dr. Administrator] Tr. at 46.

> reported to you, or discussed with you, that an abortion failed and a live birth resulted?
>
> A . . . The answer is no at the Planned Parenthood and Southwest Women's Options and the Center for Reproductive Health. There are situations in the hospital where a planned abortion, an induction of labor for a fetus, for example, with severe anomalies is born alive.
>
> Q If one of the fellows from UNM had been at Southwest, would they have been trained in what to do if a child was born alive?
>
> A I don't know.
>
> Q So does your curriculum call for training of doctors of what to do if a child is born alive because of an induced abortion?
>
> A No.
>
> Q No training at all?
>
> A No.
>
> Q There's no resuscitation training?
>
> A OB/GYN doctors do not resuscitate neonates.
>
> Q So who at the Southwest Clinic would do that resuscitation if it was necessary?
>
> . . . [A]I don't know.[835]

[Dr. Administrator] was subsequently asked about a provision in UNM's own protocol for infants that survive abortion: "When an induced abortion results in a live-born infant showing any signs of life, such as a heartbeat or voluntary movement, a birth certificate should be completed. . . . A death certificate will be completed if the infant dies."[836] When asked why such language would be included in the UNM protocol, [Dr. Administrator] expressed her ignorance of, and perhaps obliviousness to, the subject matter:

> A So I was responsible for editing and helping to draft and review this document, except for the administrative procedures. The administrative procedures are -- these are procedures that are -- that

[835] [Dr. Administrator] Tr. 24-25.
[836] [Dr. Administrator] Tr. 28-29 (quoting UNMHSC, Second Trimester Pregnancy Termination, D&E and induction of labor 2, UNM01686).

are carried out by nursing. So this -- this was added after the medical content of the document. And this -- this was added by -- by nursing.

Q Do you agree with that statement?

A So I think that—that we actually need to update this document to reflect what we—

Q Welcome to have you update it. My question is: do you agree with the statement? . . .

A So there are requirements through the hospital and through the state, and we comply with—with those requirements. I am not sure right now that these are what conform to the current requirements of the state and of the institution.

Q Do you agree with the statement?

A I don't understand your question.

Q It's a very easy question to answer. If an induced abortion results in a live-born infant showing any signs of life, such as a heartbeat, like A[P]GAR 1, or voluntary movement, a birth certificate should be completed.

A So a birth certificate is an administrative matter that I don't have an opinion about. I follow the appropriate administrative procedures as outlined by the institution and the state, but it's not something I have an opinion about.

Q So you have no opinion on whether this policy is a good policy, correct policy, what we should do, what we shouldn't do; no opinion at all?

A The medical component of this policy I stand behind. The administrative procedures, again, are not under my purview. I am very much in agreement with following the institution and the state regulations around birth certificates.

Q So is the diagnosis part of the doctor's responsibility?

A Diagnosis of what?

> Q Of a patient's situation? Is that what the doctor does, they diagnose patients? I just want to read you the rest of this paragraph, in light of diagnosis. "The diagnosis on the woman's chart should be induced abortion, secondary diagnosis giving the indication for the procedure. In addition, a diagnosis of 'live-born infant' should be made as a secondary diagnosis. This reflects the unusual outcome of the live birth from an induced abortion. Do not make an entry in the delivery room log." Where would that entry be made?
>
> A I don't know.[837]

[Dr. Administrator] would not directly answer the question whether "the decision to resuscitate a child that comes out of the birth canal" alive should be left to the woman and doctor alone, suggesting that "there is no answer" or that the answer would "depend on the individual circumstances of the patient."[838] When she was read the language of the Born-Alive Infants Protection Act and asked if she agreed with it, she responded, "I'm not familiar with the law."[839] She admitted she never discussed the law with counsel and did not "understand the relevance of this to my practice."[840]

Coming from the official who is arguably most responsible for making UNM an abortion provider and providing the same function to outside clinics—an official responsible for training in multiple competencies in abortion and family planning—this testimony is a startling reflection of the absence of attention given to any standard of care for infants that survive the abortion procedure.

When [Clinic A Dr. #1] was questioned about infants showing signs of life following abortions, she denied ever seeing such signs of life and testified that "if you want to talk about signs of life, . . . I don't know what criteria would necessarily be applied to that, but I would have to extend my knowledge of obstetrical practice."[841] She surmised that such signs would be "assessed by . . . an Apgar score, meaning respiration, color, the color of the neonate, grimace, reflexes to certain stimulus, crying," only to be challenged by Rep. Harris, whose experience as a physician includes being the chief of obstetric anesthesiology at the Johns Hopkins Hospital: "I've been in the delivery room a lot of times and witnessed Apgar scores of zero and one" on babies that were resuscitated.[842] Did she in fact conclude that "if a baby didn't grimace or didn't have reflex response to . . . painful stimulus or wasn't breathing," there was "no sign of life?" She responded, "Yes."[843] When Rep. Harris pressed further for clarification, [Clinic A Dr. #1] admitted that she was not even performing an Apgar score.[844] On "assess[ing] signs of life," she

[837] [Dr. Administrator] Tr. at 30-32.
[838] [Dr. Administrator] Tr. at 51-53.
[839] [Dr. Administrator] Tr. at 56.
[840] [Dr. Administrator] Tr. at 56-57.
[841] [Clinic A Dr. #1]Tr. at 230.
[842] [Clinic A Dr. #1] Tr. at 230-31.
[843] [Clinic A Dr. #1] Tr. at 232.
[844] [Clinic A Dr. #1] Tr. at 233.

continued, "I haven't thought about this. I have not given this deep consideration."[845] Despite the fact that SWWO performed abortions in the third trimester, the infant was not even routinely checked for a heartbeat.[846] This was the case even though [Clinic A Dr. #1] admitted there were cases in which an infant exited the womb spontaneously, before it was expected to do so.[847]

The testimony of both abortion providers suggests a lack of medical training and of any sense of obligation to be trained to preserve the life of an infant that survives the abortion procedure. It reflects a philosophy that a right to abortion somehow carries a guarantee of the death of the infant expelled during the procedure.

[845] [Clinic A Dr. #1] Tr. at 234.
[846] [Clinic A Dr. #1] Tr. at 234-35.
[847] [Clinic A Dr. #1] Tr. at 250.

VIII. Case Studies of the Fetal Tissue Industry – Planned Parenthood

Chapter VIII Redaction Key:

1. [PP Witness #1] is an abortion provider in Los Angeles, California, an executive with Planned Parenthood Federation of America (PPFA) who is in charge of the PPFA Manual of Medical Standard and Guidelines.
2. [PP Witness #2] is a manager of research projects at Planned Parenthood Gulf Coast.
3. [PP Witness #3] is a university professor, an abortion provider and serves on the PPFA National Medical Committee.
4. [PP Witness #4] works for the Consortium of Abortion Provider Services at PPFA which provides technical assistance to PPFA affiliate clinics.
5. [PP Doctor #1] is an abortion provider in Los Angeles, California, who also works for the Medical Directors' Council.
6. [PPGC Abortion Services Official] is a manager of abortion services at PPGC.
7. [PPFA Executive] works for the Medical Standards Department at PPFA
8. [PPFA Medical Officer #1] is a PPFA official who was responsible for medical issues
9. [PPFA Medical Officer #2] is a PPFA official who was responsible for medical issues
10. [PPFA Lawyer] is a legal official at PPFA.
11. [CRR lawyer] works for the Center for Reproductive Rights.
12. [ANSIRH lawyer] works for Advancing New Standards in Reproductive Health.
13. [NARAL executive] works for the Policy department at the National Abortion and Reproductive Rights Action League.
14. [StemExpress Founder and CEO] refers to the founder and CEO of StemExpress
15. [Abortion Doctor] is any doctor who provides abortions.
16. [Researcher FT] refers to any person who is involved in fetal tissue transactions.

17. [Procurement Technician] refers to any person who procures fetal tissue.

A. Summary

Planned Parenthood executives who spoke with the Panel noted that 2016 is the 100th anniversary of the founding of Planned Parenthood. A closer look at the history of the organization, however, leaves little to celebrate. The organization was founded by eugenicists who believed in limiting the rights of people to form families and have children if they had mental or physical disabilities or were of the wrong race.

Harvard studies about Planned Parenthood's business model have pointed out financial struggles the organization has faced in recent years, including smaller margins and lower revenues. Substantial evidence exists that Planned Parenthood clinics—at least 51 times—have overbilled Medicaid and improperly billed items to cover the costs of abortion services, in violation of the Hyde Amendment

During some of Planned Parenthood's difficult financial years, tissue procurement companies like StemExpress saw an opportunity to market their services to Planned Parenthood affiliate clinics and even the entire Federation. This move was welcomed by top Planned Parenthood executives, some of whom were remarkably candid about the revenue possibilities for clinics.

However, the relationship that has formed between tissue procurement companies and abortion clinics and universities is fraught with questionable practices, including the possible use of illegal, late-term abortion practices to procure the best tissues and organs, violating federal guidelines on patient consent, and systematic violations of patient HIPAA rights. The Panel has been investigating these practices for the past year.

This chapter reveals the findings of that investigation.

B. Planned Parenthood: A Corrupt Founding

According to the 2014 audited financial statement of Planned Parenthood Federation (PPFA) and related entities:

> The Federation is . . . affiliated with 68 independent medical and related entities, and 101 ancillary entities (including 34 Political Action Committees and 55-501(c)(4) organizations), all of which are separately incorporated in their respective states and which collectively constitute PPFA's membership.[848]

Planned Parenthood operates 57 affiliates directly as of 2016, a number that has been declining since 2009 based on annual reports released by the organization. In 2015, for example,

[848] Planned Parenthood Federation of America, Inc. and Related Entities: Consolidated Financial Statements and Supplementary Information 9 (June 30, 2014 and 2013), https://www.plannedparenthood.org/files/5014/1936/7155/PPFA_Audited_FS_FY2014.PDF [hereinafter PPFA 2014 Financial Statements].

PPFA oversaw 59 affiliates which operated 667 health centers (outpatient clinics) in the United States. When asked by House Energy and Commerce Committee staff why the number of affiliates has declined in recent years, PPFA attorneys responded that it is "due primarily to mergers, and in some cases disaffiliation. . . . In cases of disaffiliation, contributing factors range from compliance issues, the adoption of core services, protection of the Trademark and strategic restructuring."[849]

Until recently, PPFA also included the Planned Parenthood Foundation, which raised funds for various projects and affiliates and which was collapsed into PPFA in 2013.[850] The Planned Parenthood Action Fund (incorporated in 1989)[851] engages in public and political advocacy. Another entity, Voxent (incorporated as of 2010)[852] exists to acquire medical technology for PPFA. Additionally, PPFA maintains many programs and initiatives such as the Consortium of Abortion Providers (CAPS) which raises funds to subsidize abortion services for affiliates and provides technical assistance, including for fetal tissue programs. The PPFA also maintains three global offices.[853]

This year, 2016, marks the 100-year anniversary of Planned Parenthood. The organization has its origin in a single "birth control clinic" in Brooklyn in 1916.[854] Today it has become the highest volume abortion provider in the United States, and in 2015 alone performed 323,999 abortions.[855]

Before it was renamed Planned Parenthood in 1942, the reproductive health services provider was known as the American Birth Control League (ABCL).[856] Among the founders of the ABCL were a group of eugenicists, including Planned Parenthood founder Margaret Sanger, who sought to reduce and control population growth, including among the African American community. Sanger saw the eugenics movement as a chance to rid civilization of "racial, political and social problems."[857] In a 1921 article titled "The Eugenic Value of Birth Control Propaganda," she wrote:

> Seemingly every new approach to the great problem of the human race must manifest its vitality by running the gauntlet of prejudice, ridicule and misinterpretation. Eugenicists may remember that not many years ago this program for race regeneration was subjected to

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[849] U.S. House of Representatives Committee on Energy & Commerce Subcommittee on Oversight & Investigations Follow-Up Questions 8 (Aug. 20, 2015) [PPFA-HOU_E&C-000169], Exhibit 8.1.
[850] PPFA 2014 Financial Statements, at 9.
[851] *Id.* at 8.
[852] *Id.*
[853] Planned Parenthood website, https://www.plannedparenthood.org/about-us/planned-parenthood-global/contact-the-international-program.
[854] Planned Parenthood Minnesota, North Dakota, and South Dakota website, https://www.plannedparenthood.org/planned-parenthood-minnesota-north-dakota-south-dakota/who-we-are/history/1916-1952.
[855] Planned Parenthood Annual Report 30 (2014-2015), https://www.plannedparenthood.org/files/2114/5089/0863/2014-2015_PPFA_Annual_Report_.pdf.
[856] The Margaret Sanger Papers Project website, https://www.nyu.edu/projects/sanger/aboutms/organization_abcl.php.
[857] Margaret Sanger, *The Eugenic Value of Birth Control Propaganda* (Oct. 1921), https://www.nyu.edu/projects/sanger/webedition/app/documents/show.php?sangerDoc=238946.xml.

> the cruel ridicule of stupidity and ignorance. Today Eugenics is suggested by the most diverse minds as the most adequate and thorough avenue to the solution of racial, political and social problems. The most intransigent and daring teachers and scientists have lent their support to this great biological interpretation of the human race. . . . The doctrine of Birth Control is now passing through the stage of ridicule, prejudice and misunderstanding. . . . Gradually the criticisms are lessening—understanding is taking the place of misunderstanding. *The eugenic and civilizational value of Birth Control is becoming apparent to the enlightened and the intelligent.*[858]

Sanger believed eugenics would make the human race healthier by ridding society of people whom she saw as a burden: those who were perpetuating a cycle of poverty and illness. In her 1922 book *Pivot of Civilization*, she wrote:

> Those vast, complex, interrelated organizations aiming to control and to diminish the spread of misery and destitution and all the menacing evils that spring out of this sinisterly fertile soil, *are the surest sign that our civilization has bred, is breeding and is perpetuating constantly increasing numbers of defectives, delinquents and dependents.* My criticism, therefore, is not directed at the "failure" of philanthropy, but rather at its success.[859]

She calls those with mental disabilities a "dead weight of human waste" and a "burden of unthinking and indiscriminate fecundity." Sanger again bemoans the "perpetuation of defectives, delinquents and dependents."[860]

Further, in a 1939 report co-authored by her organization's secretary, Mary Woodward Reinhardt, and her personal secretary Florence Rose, Sanger wrote that "negroes present the great problem of the South."[861] In a letter that same year to her friend Clarence Gamble, she stressed the importance of training an African-American physician so the community will "more or less lay their cards on the table which means their ignorance, superstitions, and doubts."[862] She was concerned that African-Americans would be more open to the idea of birth control if they were speaking to a doctor who shared their race. She then wrote, "We do not want the word to go out that we want to exterminate the Negro population and the minister is the man who can straighten out that idea if it ever occurs to any of their more rebellious members,"[863] indicating—at best—that she was concerned with the growth of African-American families.

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[858] *Id.* (emphasis added).
[859] Margaret Sanger, *The Pivot of Civilization*, Chapter V: The Cruelty of Charity, http://www.gutenberg.org/files/1689/1689-h/1689-h.htm (emphasis added).
[860] *Id.*
[861] *Birth Control or Race Control? Sanger and the Negro Project,* The Margaret Sangers Papers Project, https://www.nyu.edu/projects/sanger/articles/bc_or_race_control.php.
[862] Letter from Margaret Sanger to Dr. C. J. Gamble (Dec. 10, 1939), https://libex.smith.edu/omeka/files/original/d6358bc3053c93183295bf2df1e0c931.pdf.
[863] *Id.*

For all her shocking and discriminatory statements, the organization she founded, Planned Parenthood Federation of America, has not shied away from the legacy of their founder. Since 1966, PPFA has given "individuals of distinction in recognition of excellence and leadership in further reproductive health and reproductive rights" the Margaret Sanger Award.[864] They have further appointed her grandson, Alexander Sanger, as Chair of the International Planned Parenthood Council.[865]

C. Planned Parenthood: Problems with the Business Model

In 1994, PPFA created a "reinvention team" in partnership with the Harvard Business School to address problems that PPFA saw in its affiliates. There was "a general concern that the financial condition of the national organization had deteriorated."[866] In short, net margins were declining, smaller affiliates were faring poorly, and private fundraising (20% of affiliate revenue) was declining. The nationwide rise of managed care clinics also posed several threats to PPFA, most importantly in the area of client composition.

First, most managed care plans increasingly covered the reproductive services that Planned Parenthood affiliates offered. Planned Parenthood affiliates, therefore, needed to expand their services. Private physicians also began to serve more Medicaid patients, taking a portion of Planned Parenthood's customer base with them. At the same time, the number of uninsured patients grew, increasing the demand at Planned Parenthood affiliates for reduced-cost services. The reinvention team drafted a proposal recommending a shift from a "specialty provider" model to a broad range of women-centered healthcare; creating a for-profit entity by which PPFA could distribute revenue; and restructuring governance of PPFA to add weight to the vote participation by the affiliate clinics with more clients.[867] When the draft was reviewed, some complained that "abortion was mentioned only eight times in the entire, 123-page document."[868] The second draft, therefore, "explicitly embraced protecting abortion rights as a key function."[869]

Throughout their reinvention process, the abortion giant was careful to protect its most lucrative procedure. Former Planned Parenthood facility director Abby Johnson blew the whistle on the importance Planned Parenthood placed on abortion quotas. She shared a photo in 2014 of an award given to Planned Parenthood of Aurora, Colorado, by Planned Parenthood of the Rocky Mountains "for exceeding abortion visits in the first half of FY13 compared to first half of FY12."[870] Johnson wrote on her blog that when she expressed concerns to her supervisor about the pressure to increase the number of abortions at their clinic, the supervisor "laughed and said,

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[864] Planned Parenthood website, https://www.plannedparenthood.org/about-us/newsroom/ppfa-margaret-sanger-award-winners.
[865] International Planned Parenthood Federation Western Hemisphere Region website, https://www.ippfwhr.org/en/who-we-are/alexander-sanger.
[866] Elaine V. Backman & V. Kasturi Rangan, *Planned Parenthood Federation of America (C)*, Harvard Business School, Feb. 13, 1998, at 1, Exhibit 8.2.
[867] Elaine V. Backman & V. Kasturi Rangan, *Planned Parenthood Federation of America (B)*, Harvard Business School, Oct. 21, 1997, at 2, Exhibit 8.3.
[868] *Id.* at 3.
[869] *Id.* at 4.
[870] Image of Planned Parenthood of the Rocky Mountains Certificate on LifeNews website, http://lifenews.wpengine.netdna-cdn.com/wp-content/uploads/2014/06/plannedparenthood108.png.

'But Abby, abortion is how we make our money.'"[871] Moreover, in 2010, affiliates were asked to make sure that at least one of their clinics perform abortions.[872] Based on PPFA's own numbers from annual reports, abortion accounts for about 30% of its annual income.

Almost 15 years after the initial reinvention process, in 2008, PPFA was faced with more financial troubles. According to a 2009 Harvard report:

> [The Great Recession had] further exacerbated fundraising challenges at both the local and national levels .... Everything from reduction in state family-planning budgets to worsening credit crunches to reduced donations influenced the wave of consolidations that had already been occurring throughout the organization. Reducing costs became a key focus due to continued revenue declines. Affiliates were asking themselves if there were more efficient ways of running their operations.[873]

Some Planned Parenthood executives have been remarkably candid about the financial problems faced by the organization and the abortion industry as a whole. The Panel found the following panel discussion at a national meeting:

> [PP Witness #4]: **So it's true that we have kept the price low**, but it is those of us who are in this room who have kept that price low. That, we have in some part done that to ourselves. And I understand all the reasons behind that, but that other case in point, that **we're not doing ourselves any favors by doing that.**
>
> [ANSIRH lawyer]: Yeah, I mean, and I think the tough thing is, if you have competitors in a market, I mean if you have more than one provider in a market, I think lots of providers feel like if they raise their prices at all to reflect new costs that have been imposed on them, that the other providers in the market will not do so, and then they will lose all their business and they'll go out of business. So, I think, it's, this is a really tough thing—
>
> [NARAL executive]: Or you get a Kermit Gosnell. You get a predator.
>
> [ANSIRH lawyer]: Yeah, so, yeah. I think there's a lot of areas of the country where I think people just feel that they cannot adjust their prices to reflect the actual costs because of competition, and as a result, I mean, as a result, providers are really struggling, it's also

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[871] Abby Johnson, *And Then There Were None* blog, July 22, 2014, http://archive.aweber.com/exposingthelie/A1RpD/h/Abortion_Quotas_EXPOSED_.htm.
[872] *Local Planned Parenthood Chapter Drops Affiliation*, Corpus Christi Caller Times, Dec. 20, 2010, http://archive.caller.com/news/local-planned-parenthood-chapter-drops-affiliation-ep-359672010-316353321.html.
[873] Allen Grossman, Thomas Steenburgh, Lauren Mehler, & Matt Oppenheimer, *Planned Parenthood Federation of America in 2008*, Harvard Business School, Oct. 29, 2010, at 9, Exhibit 8.4.

probably one of the most efficiently provided forms of health care in the entire country [audience laughter]. Because, you know, people have managed to just take on all these new costs without raises prices. I mean it's really quite shocking.

[PP Witness #4]: Oh I agree, I mean, and I think it's the tenacity of, again, many in this room that have hung on for so long to those early business models that have allowed it to work. **But as a long-term strategy, I don't think it's the smartest strategy we have come up with.**

[ANSIRH lawyer]: Yeah, I agree.

[CRR lawyer]: **Are you saying that maybe we should be raising prices?**

[PP Witness #4]: I think we should charge for an abortion what it costs to provide an abortion. And right now we're not. And it's at the expense of, um, at the expense of owners, and staff, and in some cases quality. And that's not good for anybody. And if regulations are going to continue to come down, whether they be TRAP regulations or just changes in health care—which I agree there's both—I think that's just something that we need to consider.

[ANSIRH lawyer]: I think that's a good point.

[PP Witness #4]: And it's a complicated case, **I mean there's going to be casualties, and there's going to be women that don't get abortions, and there's going to be women who self-induce, and there's going to be, you know, really adverse outcomes as a result, so I understand it's not a popular strategy, but I just think at some point, we can't continue to—and I don't want to have a "price-fixing conversation" [nervous laughter]—but I don't think we can continue to provide high-quality abortions for $500 a piece, and incur expenses like that we need to do for ambulatory surgical centers.** We have, are all, we all have our eggs—or all of our eggs are in a couple baskets. And if those baskets ever are no longer available, I think that, again, I think that it's not a great long-term strategy for women.[874]

Thus, for over a decade, the economic trajectory of PPFA faced challenges of market changes, management issues, and cash flow problems, even with one of the nation's top business schools trying to assist. It was at the end of this decade that organizations seeking to procure and resell fetal tissue saw an opportunity. In particular, StemExpress sought to market its services to

[874] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform FNNI0773_20150421125757 (emphasis added).

Planned Parenthood clinics and even to the whole of PPFA as a revenue enhancement. Fetal tissue donation was welcomed and even encouraged by top PPFA executives:

[PP Witness #1] said that clinics on "razor thin budget[s]" are eager to participate in fetal tissue programs:

> **But there is not a provider out there, who doesn't want this.** Everybody just sees this as a way to add another layer of good on top of what they're already doing. They already feel that what they're doing is good. Again, the majority of the providers are non-profit organizations like Planned Parenthood or operating on a razor-thin budget. So as low impact that you can be on them, the better.[875]

[PP Witness #4] admitted to undercover journalists, "We have independent colleagues who generate a fair amount of income doing this."[876] She also admitted that the national federation cannot prevent affiliates from entering into contracts with tissue procurement companies in order to increase revenue, thereby implying the need that some affiliates feel to find additional sources of revenue.[877]

In one video,[878] two journalists posing as tissue procurers are speaking to [PP Witness #4]. She seems to agree with the journalists that fetal tissue programs are indeed profitable to clinics. She even admits in a publicly released video that Planned Parenthood's independent colleagues "generate a fair amount of income doing this."[879]

> Buyer I: I was thanking [PP Witness #1] for her tip of the day; Don't bring up [unintelligible]
>
> [PP Witness #4]: It's not don't bring it up, it's . . . your headline
>
> Buyer II: What's "it?"
>
> [PP Witness #4]: The money. Making a profit off of it. What did you say?
>
> Buyer I: Just that it's financially . . .

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[875] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] at 18 (July 25, 2014) (emphasis added), Exhibit 8.5.
[876] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform 0569_20150227151723.
[877] Planned Parenthood Rep Admits Affiliates Can't Stop Harvesting, https://www.youtube.com/watch?v=_4P3oHI7KFQ&index=1&list=PLJCNTv4YXhz2JbXxCADboQK_kvOAbxxHK.
[878] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform FNNI0773_20150421063222.
[879] "Top Planned Parenthood Exec: Baby Parts Sales 'A Valid Exchange,' Can Make 'A Fair Amount of Income,'" https://www.youtube.com/watch?v=c9EU_02c5bM.

> [PP Witness #4]: Profit [trails off]
>
> Buyer I: . . . beneficial to the clinic . . .
>
> [PP Witness #4]: But the truth is, is that some [Planned Parenthood affiliates] might want to do it [fetal tissue donation] for, to increase their revenues. **And we can't stop them**. We only have carrots and sticks.[880]

[PP Doctor #1] said in a conversation with the journalists posing as a tissue procurement company about remuneration for fetal tissue, "Well, you know in negotiations the person who throws out the figure first is at a loss, right? . . . I don't want to play games, I just don't want to lowball, because I'm used to low things from . . . [trails off]."[881]

In a another video,[882] a journalist is speaking to [Abortion Doctor] of Planned Parenthood New York City about fetal tissue remuneration. The following transcript recounts their conversation:

> [Abortion Doctor]: Okay, yeah, that's great, and I think that the fact there's like a, like for me, just like somebody would take it is great, but I think a financial incentive from you guys is going to be like to, I think we have to get this approved, but [we?] will be very happy about it, so—
>
> Buyer: Right, the financial incentive would make people happy.
>
> [Abortion Doctor]: Yeah, exactly.
>
> Buyer: Is that what I'm hearing you saying?
>
> [Abortion Doctor]: Yeah, absolutely!

In fact, Planned Parenthood's own job descriptions discuss the need to increase "revenue." The job description for Reproductive Health/Abortion and/or Prenatal Program Coordinator[883] at Planned Parenthood Mar Monte lists under Essential Duties, "contribute to achieving health center productivity goals."[884]

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[880] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform FNNI0773_20150421063222.

[881] Center for Medical Progress, Transcript of Meeting with [PP Doctor #1] at 9-10 (Feb. 6, 2015) (emphasis added), Exhibit 8.6.

[882] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNPB0298_20150421080120.

[883] While this position includes delivery of and referring for prenatal care, PPFA performed 18.6 abortions for every 1 prenatal service in 2014. *See* PPFA Annual Report (2014-2015), https://www.plannedparenthood.org/files/2114/5089/0863/2014-2015_PPFA_Annual_Report_.pdf.

[884] Job description [PPMM-SIP_E&C-000023-000025], Exhibit 8.7.

Similarly, at the same affiliate, an Essential Duty of the Health Center Manager is to manage "the health center to meet or exceed goals in productivity, financial performance and client visits."[885]

The same duty was seen on many other job descriptions at other affiliates for a variety of positions. For example, the position of Mid-Level Clinician at Planned Parenthood Los Angeles included under General Duties, "Participate in health center/affiliate efforts to achieve established revenue cycle goals."[886]

The position of Medical Assistant III-Specialty Services at Planned Parenthood Pacific Southwest also said under Essential Functions, "Participate in health center/affiliate efforts to achieve established revenue cycle goals."[887]

D. PPFA – Affiliate Relationship

PPFA invites abortion clinics to become affiliates and thereby join the Federation. The Panel has learned through interviews with Planned Parenthood executives that affiliates undergo accreditation by the national office.[888] Periodically, a team inspects each affiliate clinic and reports on any violations they see.[889] PPFA requires a wide range of accreditation compliance, use of internal manuals, and obedience to policy directives designed to ensure compatibility with PPFA policy. This compliance includes rules and guidelines that address donation of fetal tissue for research or transplantation. The Panel examined one particular manual titled the *PPFA Manual of Medical Standards and Guidelines* (MS&G), which is updated every two years. The MS&G sets guidelines for affiliate conduct that impacts the transfer of fetal tissue. The Panel conducted interviews with PPFA executives to better evaluate the implementation of the guidelines as they apply to the accreditation process at the affiliate clinic level. Affiliated clinics are subject to "accreditation reviews," which are conducted every three or four years.

To qualify for affiliation, clinics must offer the core services as determined by PPFA. The list of PPFA Core Services includes:

- Well Woman Exams, including cervical screening and breast exams
- Pregnancy Testing and Options Education
- Contraception, Education, Prescribing/Dispensing for all FDA approved methods
- STI screening, testing, treatment for women and men
- HIV Point of Service Rapid Testing for Women and Men
- HPV Vaccine[890]

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[885] Job description [PPMM-SIP_E&C-000034-000036], Exhibit 8.8.
[886] Job description [PPLA-SIP_E&C-000093-000095], Exhibit 8.9.
[887] Job description [PPPSW-SIP_E&C-000004-000006], Exhibit 8.10.
[888] Transcribed Interview of [PP Witness #1] at 25-26 (Oct. 6, 2016), Exhibit 8.11.
[889] *Id.* at 58.
[890] U.S. House of Representatives, Committee on Energy & Commerce, Subcommittee on Oversight & Investigations Follow-Up Questions at 2 (Aug. 20, 2015) [PPFA-HOU_E&C-000163-000164], Exhibit 8.1.

"Additionally, abortion services must be offered in at least one health center per affiliate, as follows: First Trimester medical abortion; AND/OR First Trimester surgical abortion."[891] Each of these "core services" involves a financing source, often federal or state taxpayer funding.[892]

Another aspect of affiliate oversight is performed by the Consortium of Abortion Providers (CAPS), a unit within the PPFA. [PP Witness #3] told the Panel that "CAPS advises affiliates and supports affiliates that provide abortion services in doing their job better."[893] .... [PP Witness #4] told Panel staff, "if an affiliate at Planned Parenthood requests technical assistance, whether that be for clinical services or other, we will provide those technical services for them. We will consult with them. We will provide onsite assistant."[894]

PPFA relies upon the 1000-page guidance document, *The Medical Standards and Guidelines* (MS&Gs) to regulate affiliate practices and policies. They "are the clinical guidelines that all affiliates follow in terms of core services to provide their care."[895] According to [PP Witness #1] whose duties include oversight of the MS&G, "The accreditation team develops a list of accreditation indicators. They draw those indicators from a variety of documents, one of which is the Standards and Guidelines, and then they use that when they do their accreditation visits."[896]

The Panel sought to understand whether a significant "management gap" exists between the PPFA written guidance, specifically the MS&G and the clinical practices of affiliates. Inadequate compliance with internal management requirements, when they include federal law and regulation are questions that Congress seeks to have answered in light of the large amount of federal funding the PPFA receives. The PPFA national office reviews and approves research projects at the affiliates. [PP Witness #3] told Panel staff, "If an affiliate is proposing to initiate or become involved in a research project, the affiliate presents information about that project to the National Research Office."[897] The relationship between management and affiliates was further explained as follows:

- [PP Witness #1]: "An affiliate undergoes accreditation by the national office . . .[898]
- [PP Witness #1]: "If an accreditation team was at an affiliate doing an accreditation visit and notes there was a violation of one of the policies, they would make a notation of it, whatever the policy was."[899]

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[891] *Id.* at 3.
[892] See Chapter II.D.2 *supra*.
[893] Transcribed Interview of [PP Witness #3] at 12 (Nov. 1 2016), Exhibit 8.13.
[894] Transcribed Interview of [PP Witness #4] at 11 (Nov. 17 2016), Exhibit 8.14.
[895] Transcribed Interview of [PP Witness #3] (Nov. 1, 2016). See above for list of core services, Exhibit 8.13.
[896] Transcribed Interview of [PP Witness #1] at 26 (Oct. 6 2016), Exhibit 8.11.
[897] Transcribed Interview of [PP Witness #3] at 34 (Nov. 1, 2016), Exhibit 8.15.
[898] Transcribed Interview of [PP Witness #1] at 25-26 (Oct. 6, 2016), Exhibit 8.11.
[899] Transcribed Interview of [PP Witness #1] at 58 (Oct. 6, 2016), Exhibit 8.12.

- [PP Doctor #1]: IF you are an affiliate you apply to [the] medical division for permission [to conduct fetal tissue donation].[900]

- [PP Witness #3]: "CAPS advises affiliates and supports affiliates that provide abortion services in doing their job better . . . . MS&Gs are the clinical guidelines that all affiliates follow in terms of core services to provide their care"[901]

- [PP Witness #3]: "If an affiliate is proposing to initiate or become involved in a research project, the affiliate presents information about that projeet to the National Research Office."[902]

- [PP Witness #3]: "My main job as Senior Medical Advisor was the creation of and guidance of a national quality improvement department. All the affiliates already have their own quality improvement departments or sorts of departments like that, but we did not have a unified national effort, and we now like everybody else use electronic medical records. . . . We provide quarterly reports to all of our affiliates on their outcomes. . . ."[903]

- [PP Witness #3]: "Planned Parenthood has actually always done research. At the time it was founded there was a branch of the federal 100 years ago called the Planned Parenthood Research Bureau that worked on developing new contraceptives, and so there's a long history of research at Planned Parenthood, but most recently we've made a concerted effort to think about as an organization where we can contribute."[904]

- [PP Witness #3]: "In looking back to when I was chair of the National Medical Committee is when Planned Parenthood instituted the concept of poor medical services for the first time, and surveys showed that most affiliates back then did provide most services, but this was really a way to codify that women's preventive screening, care for sexually

[900] [PP Doctor #1] Briefing with the House Energy and Commerce Committee at 3.b.iii.4.b (Sept. 18, 2015), Exhibit 8.16.
[901] Transcribed Interview of [PP Witness #3] at 12 (Nov. 1, 2016), See Exhibit 8.13.
[902] Transcribed Interview of [PP Witness #3] at 34 (Nov. 1, 2016), Exhibit 8.15.
[903] Transcribed Interview of [PP Witness #3] at 93 (Nov. 1, 2016), Exhibit 8.17.
[904] Transcribed Interview of [PP Witness #3] at 95 (Nov. 1, 2016), Exhibit 8.18.

> transmitted infections. All contraceptive services and abortion services were tied together in the core mission and needed to be available to all of our patients."[905]

The Panel noted that despite these affirmations of a closely managed organization by several of its key leaders, the Panel found instead a management gap of significant proportions.

E. Planned Parenthood Federation Failure to Ensure Compliance by: Affiliates with Legal Billing Practices; Federal Law Governing Fetal Tissue Donation Projects; Federally Required Affirmation about Changing Abortion Procedures; Patient Consent; and HIPAA Regulations.

1. Summary

The Panel sought to understand even more broadly whether the trajectory of the economic business culture and compliance control exercised by PPFA influenced clinical practice of its affiliate clinics. Significant deficiencies described below were revealed by the investigation.

First, the clinics have a checkered history of overbilling Medicaid and of improperly billing items to cover the costs of abortion services, in violation of the Hyde Amendment.

Second, the clinics did not follow PPFA guidance about compliance with federal criminal statutes that govern the terms of fetal tissue donation. Accounting documents from middleman tissue organizations showed that several PPFA affiliates made a profit from the transfer of fetal tissue.

Third, PPFA failed to secure compliance with the requirement that doctors who perform abortions certify in writing that the method of abortion has not been changed to facilitate fetal tissue donation. The PPFA executive in charge of this requirement admitted that she regularly changed the method of abortion to facilitate intact fetal specimens and further admitted that she had never certified that the method of abortion was not altered.

Fourth, PPFA guidance on patient consent and the affiliate practice violates federal consent regulations.

Fifth, the affiliate clinics routinely violated HIPAA privacy regulations to facilitate the harvesting of fetal tissue for which the clinics were paid on a per specimen basis.

2. Planned Parenthood: Failure to Properly Steward Federal Funds

The Panel sought to understand participation in fetal tissue transfer within the context of the affiliate clinics' general business practices and financial stability. Participation in fetal tissue donation requires competent accounting and record-keeping practices as well as fiscal precision in recordkeeping to prevent any possibility of violating the prohibition against profiting from the

[905] Transcribed Interview of [PP Witness #3] at 98 (Nov. 1, 2016), Exhibit 8.19.

sale of fetal tissue. Thus, the Panel reviewed the history of Planned Parenthood's stewardship of federal and state funds designated for family planning and other women's health concerns.

This review sought to identify whether the individual clinics maintained accounting practices that guaranteed the separation of federal funds designated for family planning from funds that paid for abortion procedures. The Panel found a significant history of flawed and unlawful management of federal funds by Planned Parenthood.[906] Planned Parenthood's improper practices were revealed primarily through audits performed by the Office of Inspector General at the U.S. Department of Health and Human Services and by state-level family planning agencies. Of particular concern is the clinics' false designation of abortion services as family planning services. This practice misallocates federal funds designated for family planning to underwriting abortion procedures, a violation of the provisions of the Hyde Amendment.

It is difficult to discern exactly how much funding Planned Parenthood receives from the government. Planned Parenthood's own annual reports over recent years report the following:

FY 2002: $240.9 million[907]	FY 2007: $336.7 million[908]	FY 2012: $542.4 million[909]
FY 2003: $254.4 million[910]	FY 2008: $349.6 million[911]	FY 2013: $540.6 million[912]
FY 2004: $265.2 million[913]	FY 2009: $363.2 million[914]	FY 2014: $528.4 million[915]
FY 2005: $272.7 million[916]	FY 2010: $487.4 million[917]	FY 2015: $553.7 million[918]

[906] During the Panel's investigation, it discovered numerous "reports" about Planned Parenthood. Panel staff met with personnel from the Office of Inspector General from HHS and reviewed numerous publicly available audits of Planned Parenthood. During its investigation, research by the Charlotte Lozier Institute and the Alliance Defending Freedom was provided to the Panel. This section substantially relies upon reporting by the Charlotte Lozier Institute and the Alliance Defending Freedom.

[907] Planned Parenthood Annual Report (2001-2002), http://prolifeaction.org/wp-content/uploads/docs/pp/PPAnnualReport2001-2002.pdf.

[908] Planned Parenthood Annual Report (2006-2007), http://liveaction.org/research/wp-content/uploads/2011/06/2006-2007-Planned-Parenthood-Annual-Report.pdf.

[909] Planned Parenthood Annual Report (2011-2012), https://www.plannedparenthood.org/files/4913/9620/1413/PPFA_AR_2012_121812_vF.pdf.

[910] Planned Parenthood Annual Report (2002-2003), http://prolifeaction.org/wp-content/uploads/docs/pp/PPAnnualReport2002-2003.pdf.

[911] Planned Parenthood Annual Report (2007-2008), http://www.mdrtl.org/files/PP_AnnualRpt08_vFinal.pdf.

[912] Planned Parenthood Annual Report (2012-2013), https://www.plannedparenthood.org/files/7413/9620/1089/AR-FY13_111213_vF_rev3_ISSUU.pdf.

[913] Planned Parenthood Annual Report (2003-2004), http://www.plannedparenthoodrx.com/annualreport/report-04.pdf.

[914] Planned Parenthood Annual Report (2008-2009), http://www.toomanyaborted.com/wp-content/uploads/2010/PDFs/PP_AR_011011_vF-1.pdf.

[915] Planned Parenthood Annual Report (2013-2014), https://www.plannedparenthood.org/files/6714/1996/2641/2013-2014_Annual_Report_FINAL_WEB_VERSION.pdf.

[916] Planned Parenthood Annual Report (2004-2005) http://www.stopp.org/PPFAReports/PPFA200405002.pdf.

[917] Planned Parenthood Annual Report (2009-2010) http://liveaction.org/research/wp-content/uploads/2011/06/2009-2010-Planned-Parenthood-Annual-Report.pdf.

[918] Planned Parenthood Annual Report (2014-2015) https://www.plannedparenthood.org/files/2114/5089/0863/2014-2015_PPFA_Annual_Report_.pdf.

FY 2006: $305.3 million[919] FY 2011: $538.5 million[920]

However, the General Accounting Office reports receipt of only $657.1 million, with International Planned Parenthood Federation receiving $3.9 million.[921] The discrepancy is the indirect funding the Planned Parenthood receives from Title XIX Medicaid reimbursements. Any accountability of the individual clinics relies upon the auditing resources of the state and federal inspector generals.

3. Recent History of Planned Parenthood Audits

There have been 51 external audits of Planned Parenthood affiliates. These audits are summarized below. Additionally, there have been 61 federal audits of state family planning agencies. The consistent pattern is the practice of billing of abortion procedures as family planning or other services such as STD testing. One practice called "unbundling" or "fragmentation" consists of schemes that bill for several types of allowed services to "cover" the non-allowed costs of an abortion.

Limited resources and the volume of Medicaid reimbursement billing make it impossible to audit all federal Medicaid reimbursements. In fact, by design the audits summarized below reflect a very small sample of the total Medicaid reimbursements received by Planned Parenthood. For example, during a review of a New York Planned Parenthood affiliate, $11,818,856.30 was paid for services rendered to 21,413 patients during the audit period. The review itself consisted of a random sample of 100 patients with Medicaid payments of $53,977.99. The narrow sample also pales when compared to a GAO estimate that in Fiscal Year 2013 there were $14.4 billion in improper Medicaid payments.[922]

Audits of Planned Parenthood Affiliates: Audited Years and Averages[923]

State	Audited Years	Total Overbilling	Overbilling by Audited Year
California	1	$5,213,645.92	$5,213,645.92

[919] Planned Parenthood Annual Report (2005-2006) http://liveaction.org/research/wp-content/uploads/2011/06/2005-2006-Planned-Parenthood-Annual-Report.pdf.
[920] Planned Parenthood Annual Report (2010-2011) https://issuu.com/actionfund/docs/ppfa_ar_2011_110112_vf.
[921] *See* U.S. GOVERNMENT ACCOUNTABILITY OFFICE, FEDERAL FUNDS: FISCAL YEARS 2002-2009 OBLIGATIONS, DISBURSEMENTS, AND EXPENDITURES FOR SELECTED ORGANIZATIONS INVOLVED IN HEALTH-RELATED ACTIVITIES (GAO-10-533R) (2010), at Table 7, http://www.gao.gov/new.items/d10533r.pdf; *see also id.* at Tables 10, 16, 18.
[922] U.S. GOVERNMENT ACCOUNTABILITY OFFICE, MEDICAID PROGRAM INTEGRITY: INCREASED OVERSIGHT NEEDED TO ENSURE INTEGRITY OF GROWING MANAGED CARE EXPENDITURES (GAO-14-341) (2014), at 2 (citing a figure calculated by the Centers for Medicare & Medicaid Services (CMS), the federal agency within the Department of Health and Human Services (HHS) that oversees Medicaid).
[923] Charlotte Lozier & Alliance Defending Freedom, *Profit. No Matter What.* (Nov. 1. 2016).

Connecticut	unknown	$18,791.00	unknown
Illinois	2	$387,000.00	$193,500.00
Louisiana	1	$6,147.18	$6,147.18
Louisiana	1	$0	$0
Maine	5.02	$33,294.83	$6,632.44
Nebraska	0.166	$3537.00	$21,307.23
New York – I	unknown	$207,809.00	unknown
New York – II	1	$15,723.91	$15,723.91
New York – III	2	$1,254,603.00	$627,301.50
New York – IV	1	$886.26	$886.26
[New York – V	3	$112,490.31	$37,496.77
[New York – VI	3	$12,031.29	$4,010.43
[New York – VII	3	$11,539.48	$3,846.49
Ohio	unknown	$0	$0
Oklahoma	unknown	unknown	unknown
Oklahoma	unknown	unknown	unknown
Oklahoma	unknown	unknown	unknown
Texas – I	unknown	$409,675.10	unknown
Texas – II	1.58	$129,028	$81,663
Washington – I	unknown	unknown	unknown
Washington – II	2.96	$629,142.88	$212,548.27
Washington – III	unknown	$11,453	unknown
[Wisconsin – I	0.75	$450.39	$600.52
[Wisconsin – II	0.75	$1,276.31	$1,701.75
[Wisconsin – III	0.75	$135.18	$180.24

[Wisconsin – IV	0.75	$128.28	$171.04
Wisconsin – V	1	$74.28	$74.28
[Wisconsin – VI	2	$368.51	$184.26
[Wisconsin – VII	2	$467.02	$233.51
[Wisconsin – VIII	2	$381.99	$191.00
[Wisconsin – IX	2	$404.59	$202.30
[Wisconsin – X	2	$2,533.46	$1,266.73
[Wisconsin – XI	2	$277.31	$138.66
[Wisconsin – XII	2	$613.19	$306.60
[Wisconsin – XIII	2	$773.84	$386.92
Wisconsin – XIV	1	$1,864.42	$1,864.42
[Wisconsin – XV	3	$800.00	$266.67
[Wisconsin – XVI	3	$5,139.71	$1,713.24
[Wisconsin – XVII	3	$1,968.71	$656.24
[Wisconsin – XVIII	3	$2,096.00	$698.67
[Wisconsin – XIX	3	$13,270.11	$4,423.37
[Wisconsin – XX	3	$468.71	$156.24
[Wisconsin – XXI	3	$2,198.13	$732.71
[Wisconsin – XXII	3	$700.00	$233.33
[Wisconsin – XXIII	3	$3,200.00	$1066.67
[Wisconsin – XXIV	3	$1,100.00	$366.67
[Wisconsin – XXV	3	$378.40	$126.13
Wisconsin – XXVI	1	$2,204.26	$2,204.26
Wisconsin – XXVII	1	$52,193.24	$52,193.24
TOTAL	**83.726**	**$8,552,264.20**	**$6,497,049.07**

4. Summary Details of the Known Audits of Planned Parenthood Affiliates

Approximately one-third of Planned Parenthood's 57 U.S. affiliates[924] have been audited. Each audit typically considers only a small sampling of the total accounting records for a selected period of time. Thus, a reasonable extrapolation is possible about the audited organizations financial practices.

l) California Audits

i) California Audit I – San Diego and Riverside Counties, 2004

The California Health and Human Services Agency, Department of Health Services conducted the audit of paid claims to Planned Parenthood San Diego and Riverside Counties (PPSDRC) from July 1, 2002, to June 30, 2003, for Codes X1500 (contraceptive barrier products) and X7706 (oral contraceptives), and February 2, 2003, to May 30, 2004 for Code X7722 (Plan B products).

The audit revealed that (PPSDRC) had received a deep discount from the manufacturer on certain products and should still be allowed to bill the State of California as though they had paid a normal wholesale price.

Due to this noncompliance, (PPSDRC) was compelled to repay $5,213,645.92.

ii) California Audit II – Golden Gate, 2010

An Internal Revenue Service criminal investigative audit of PPFA affiliate Planned Parenthood Golden Gate (PPGG) discovered substantial losses for the 2009 tax year and inaccurate information in the PPGG tax returns.[925] PPFA had already conducted an accreditation review of PPGG in 2004, during which the affiliate failed five of PPFA's nine indicators of financial health. In a 2010 warning letter, the California Attorney General's Charitable Trusts Division cited PPGG Action Fund, PPGG's political advocacy and public policy arm, for failure to file its tax documents with that office for at least 10 years.[926]

m) Connecticut Audit

The U.S. HHS-OIG conducted an audit of Planned Parenthood of Connecticut Inc. & Subsidiar., finding $18,791 in overbilling.[927]

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[924] Planned Parenthood website, *see* Local & State Offices, http://www.plannedparenthood.org/about-us/local-state-offices.

[925] *See also* Katharine Mieszkowski, *IRS Looking into Planned Parenthood Golden Gate After Complaint*, THE BAY CITIZEN, Sept. 2, 2010, https://www.baycitizen.org/news/health/irs-looking-planned-parenthood-after/.

[926] *See, e.g.*, Katharine Mieszkowski, *Internal Concerns About Fiscal Health and Tax Documents Suggest Long-Term Disarray*, THE BAY CITIZEN, Aug. 12, 2010, https://www.baycitizen.org/news/health/financial-docs-raise-questions-about/.

[927] A-01-99-59104, released Aug. 1999. *See* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, SEMIANNUAL REPORT OCTOBER 1, 1999 – MARCH 31, 2000 (2000), at D-8,

n) Illinois Audit

This audit by the Illinois Department of Healthcare and Family Services' Inspector General of Planned Parenthood of Illinois (PPIL) found 641 missing records, 31 instances of billing for non-covered services, and 10 instances of billing for services actually performed by someone else, as well as improper procedure codes. As a result of the audit,[928] PPIL and its medical director, Caroline Hoke, agreed to repay the state $367,000 to settle findings of Medicaid overbilling and failure to document services allegedly provided, primarily contraceptives.[929]

o) Louisiana Audits

i) Louisiana Audit I

As the result of an audit conducted by the Louisiana Department of Health and Hospitals (DHH), one Planned Parenthood clinic repaid $6,147.18 to DHH to settle findings of improper billings.[930]

ii) Louisiana Audit II – 2014

In response to Louisiana Senate Concurrent Resolution No. 57 and House Resolution No. 105, 2013 Regular Session, Louisiana's Legislative Auditor reviewed Planned Parenthood Gulf Coast's billings during calendar year 2012. In a report issued February 19, 2014, the legislative auditor found that overall, they could find no evidence that PPGC's billings were not allowable, and that they had no evidence of PPGC pressuring clients into abortion.[931]

p) Maine Audit

The Maine Department of Health and Human Services audited Planned Parenthood of Northern New England (PPNNE), finding that PPNNE billed nearly double its acquisition costs for Levonorgestrel IUDs. PPNNE agreed to repay the state $33,294.83.[932]

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https://oig.hhs.gov/publications/docs/semiannual/2000/00ssemi.pdf. Charlotte Lozier Institute is working to obtain full audit records.

[928] This audit, case number 1074160, covered the period January 1, 2006, to December 31, 2007.

[929] *See* Andrew L. Wang, *Planned Parenthood Settles with Illinois on Medicaid Payments*, MODERN HEALTHCARE, Sept.6,2012,http://www.modernhealthcare.com/article/20120906/
INFO/309069993; Andrew L. Wang, *Medicaid Probes Planned Parenthood Fees*, CRAIN'S CHICAGO BUSINESS, July 9,2012http://www.chicagobusiness.com/article/20120707/
ISSUE01/307079977/medicaid-probes-planned-parenthood-fees.

[930] Specifically, the clinic had billed clinic services under the laboratory Medicaid provider code and vice versa.

[931] However, Louisiana sources report that Planned Parenthood is not currently performing abortions in Louisiana, making allegations of abortion referrals more difficult to track.

[932] *See* Letter from Herbert F. Downs, Director of Audit, Maine Department of Health and Human Services, to [redacted] (June 21, 2012) (on file with Charlotte Lozier Institute). The original audit finding was $90,169.27 in overbillings. Letter from Michael Bishop, Auditor II, Program Integrity,

q) Nebraska Audit

The Nebraska Auditor of Public Accounts audited Planned Parenthood of the Heartland (PPH) and other organizations that receive $500,000 or more in federal funds. PPH was found to have billed and been paid $3,537 for abortion expenses.

r) New York Audits

i) New York Audit I – New York City, January 2009

A January 2009 audit of Planned Parenthood of New York City, Inc. (PPNYC)/Margaret Sanger Center resulted in PPNYC electing to repay the amount of $207,809.00.[933]

ii) New York Audit II – Hudson Peconic, June 2009

A June 2009 audit of Medicaid payments for family planning and reproductive health services paid to Planned Parenthood Hudson Peconic, Inc. (PPHP) on behalf of Medicaid beneficiaries while they were enrolled in Community Choice Health Plan and Health Insurance Plan of New York found significant overpayments for family planning and reproductive health services claims, resulting in an overpayment of $15,723.91, inclusive of interest.[934]

iii) New York Audit III – New York City, June 2009

A June 2009 audit of payments to PPNYC/Margaret Sanger Center for diagnostic and treatment center services paid by Medicaid found improper practices, with sample overpayments of $7,960.01 and total overpayments of at least $1,254,603.00. During the audit period, $11,818,856.30 was paid for services rendered to 21,413 patients. The review consisted of a random sample of 100 patients with Medicaid payments of $53,977.99.[935]

iv) New York Audit IV – New York City, December 2009

A December 2009 audit of Medicaid payments for family planning and reproductive health services paid to PPNYC/Margaret Sanger Center on behalf of Medicaid beneficiaries while they were enrolled in VidaCare Inc. found overpayments, inclusive of interest, of $886.26.

The audit found that PPNYC had improperly billed Medicaid $719.55 for family planning and reproductive health services that were rendered to VidaCare enrollees; as a result,

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Financial Services – Audit, Maine Department of Health and Human Services, [redacted] (Dec. 14, 2010).

[933] Audit # 08-3045.

[934] The audit (Family Planning Chargeback to Managed Care Network Providers, 09-1415, June 10, 2009) covered the period Jan. 1, 2004, through Dec. 31, 2004.

[935] The audit (06-6696) covered the period Jan. 1, 2004, through Dec. 31, 2005.

18 NYCRR § 515.2 and § 540.6 requirements were violated. OMIG then calculated $166.71 in interest, resulting in $886.26 in required restitution. PPNYC was invited to respond to the draft report but did not do so within 30 days as directed. [936]

v) New York Audits V-VII – February/May 2010

Three audits conducted of New York Planned Parenthood affiliates found six categories of overbilling, resulting in a total overpayment of $136,061.08, inclusive of interest. The audits found total overpayments of $136,061.08.[937]

s) Oklahoma Audits

In three apparently separate audits covering the Planned Parenthood affiliates in Oklahoma, Planned Parenthood of Central Oklahoma, Inc., and Planned Parenthood of the Heartland, auditors found overbilling rates of 14.1%, 18%, and 20.3%.[938]

t) Texas Audits

i) Texas Audit I

On June 30, 2009 Planned Parenthood Center of El Paso closed its seven centers for financial reasons and filed for bankruptcy. The closure led to an audit by Texas Department of State Health Services (DSHS). The audit revealed numerous example of fiscal mismanagement, including unpaid subcontractors in the amount of $529,707.97. The OIG determined that PPCEP was not in compliance with the applicable DSHS contracts since it had requested DSHS reimbursement for subcontractor billings it had never paid. Subcontractors identified the outstanding billings as totaling $529,707.97.[939]

ii) Texas Audit II

The U.S. Department of Health and Human Services, Office of the Inspector General, released an audit[940] of the Texas Health and Human Services Commission that revealed missing

[936] The audit (Family Planning Chargeback to Managed Care Network Providers, 09-4845, Dec. 16, 2009) covered the period Jan. 1, 2005, through Dec. 31, 2005.

[937] The audits of PPHP (Prenatal Care Assistance Program, 2009Z33-136W, May 27, 2010), Planned Parenthood of Nassau County, Inc. (PPNC) (Prenatal Care Assistance Program, 2009Z33-083W, May 27, 2010), and Planned Parenthood of South Central New York, Inc. (PPSCNY) (Prenatal Care Assistance Program, 2009Z33-048O, Feb. 24, 2010) covered the period Jan. 1, 2006, through Dec. 31, 2008.

[938] *See* Letter from Mary Fallin, Governor, State of Oklahoma, to Nico Gomez, Director, Oklahoma Health Care Authority Board (Nov. 18, 2015) (on file with Charlotte Lozier Institute); *see also, e.g.*, Kate Richey, *What Really Happened with WIC?*, OKLAHOMA POLICY INSTITUTE, Oct. 24, 2012, http://okpolicy.org/what-really-happened-with-wic/. Charlotte Lozier Institute is working to obtain full audit records.

[939] *See Financially Troubled Planned Parenthood of El Paso Closes Doors*, LIFESITENEWS.COM, July 1, 2009, http://www.lifesitenews.com/news/financially-troubled-planned-parenthood-of-el-paso-closes-doors.

[940] The audit (Texas Claimed Unallowable Federal Reimbursement for Some Family Planning Services, A-06-11-00016) covered the period Mar. 1, 2007, through Sept. 30, 2008.

documentation and overbilling of $129,028 ($67,019 from Medicaid and $62,009 from the waiver program).

u) Washington State Audits

There are three known Washington State audits of Planned Parenthood affiliates. In sum, they uncovered overpayments of at least $640,595.88, inclusive of interest.

i) Washington Audit I

In 2000 and 2001, an audit of a Planned Parenthood clinic uncovered "inflated billings;" a lengthy analysis and negotiation process resulted in an untenable and apparently illicit agreement.[941]

ii) Washington Audit II – Inland Northwest, 2007-2009

A 2007-2009 audit of the Planned Parenthood of the Inland Northwest (PPINW) affiliate[942] found numerous instances of overbilling or other irregularities, resulting in an overpayment of $629,142.88, inclusive of interest.[943]

iii) Washington Audit III – Great Northwest

In May 2012, Planned Parenthood of the Great Northwest (PPGNW) reimbursed the Medicaid program $11,453 as a result of a sample audit conducted by the Washington Medicaid Fraud Control Unit (MCFU) as the result of complaints from concerned citizens alleging "questionable billing practices." Additionally, one portion of the audit that related to a particular type of contraceptive billing was provided to the U.S. Attorney's office for independent investigation.[944]

v) Wisconsin Audits

The State of Wisconsin has released 26 audits it conducted of Planned Parenthood of Wisconsin from 2006-2012. These 26 audits uncovered total potential overpayments of at least $43,272.80. Another audit conducted of Planned Parenthood of Wisconsin revealed an additional $52,193.24 for family planning in 2014. These audits are summarized below:

- # 2006 37543 (Milwaukee - West Wisconsin Avenue): $450.39
- # 2006 50088 (Kenosha): $1,276.31

[941] Email from Myra S. Davis, Medical Assistance Administration Rules and Publications, to Heidi Robbins Brown, Deputy Assistant Secretary, Medical Assistance Administration, Washington Department of Social and Health Services (Sept. 17, 2004, 11:56 PDT) (on file with the Alliance Defending Freedom).
[942] Doing business as Planned Parenthood of Spokane.
[943] The audit (MA 07-13, July 20, 2009) was conducted May 8-10, 2007.
[944] Audit # 09-04-08, of Yakima County.

- # 2006 96759 (Milwaukee - North Jackson Street): $135.18
- # 2006 98176 (Milwaukee - North Jackson Street): $128.28
- # 2007 03883 (Appleton): $368.51
- # 2007 27407 (Madison): $467.02
- # 2007 29154 (Sheboygan): $381.99
- # 2007 49325 (Waukesha): $404.59
- # 2007 66774 (Milwaukee): $2,533.46
- # 2007 70591 (Chippewa Falls): $277.31
- # 2007 86622 (Fond du Lac): $613.19
- # 2007 88039 (Kenosha): $773.84
- # 2010 15792 (Madison): $800.00
- # 2010 38805 (Milwaukee - West Wisconsin Avenue): $5,139.71
- # 2010 55068 (Kenosha): $1,968.71
- # 2010 75330 (Beaver Dam): $2,096.00
- # 2010 22240 (Racine): $13,270.11
- # 2010 34897 (Green Bay): $468.71
- # 2010 39809 (Waukesha): $2,198.13
- # 2010 40664 (Shewano): $700.00
- # 2010 46459 (Chippewa Falls): $3,200.00
- # 2010 58443 (Fond du Lac): $1,100.00
- # 2010 84963 (Milwaukee - South 7th Street): $378.40

5. Conclusion

There are three important conclusions the Panel reached regarding Planned Parenthood's stewardship of federal funds. First, local affiliates regularly and with little accountability substitute billing codes for approved reimbursements for prohibited activities that violate the prohibition against use of federal funds for abortion services. Second, the affiliates operate with disregard of accepted accounting procedures. Third, the local affiliates that seek to increase Medicaid payment through false billing practices also require close scrutiny about compliance with federal law on receiving valuable consideration for the transfer of fetal tissue.

6. Compliance with Federal Law Governing Fetal Tissue Donation Programs

As early as April 4, 2001, chief executives of affiliate clinics were directed via written memorandum by PPFA executives to follow federal regulations for aborted pregnancy donation programs. The memorandum reminded affiliates that fetal tissue donation is governed by federal laws:

> Fetal tissue donation programs are governed by two federal laws, the National Organ Transplant Act (42 U.S.C. 274e) (NOTA) and the NIH Revitalization Act of 1993 (42 U.S.C. 289g-1 and 2) (NIHRA). These laws, particularly NIHRA, govern many aspects of fetal tissue donation programs, and the attached Standard addresses

> all of these issues that affect medical practice and clinical functions.[945]

The memorandum warned that:

> These laws also forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage" of fetal tissue. In addition, NOTA permits reasonable payments for the "removal" of fetal tissue when the research is supported by federal funds. (These laws do not affect a provider's ability to charge its normal and customary fee for the abortion.)[946]

Affiliates were advised that compliance with the requirements of these laws could be achieved in one of two ways:

> 1. One method would be to recover *no costs* associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.[947]
>
> 2. The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred *by the affiliate* in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.[948]
>
> Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a credible and good-faith computation of the actual cost of the space

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[945] Email from [PP Witness #1] and [PPFA Executive], (Jan. 26, 2011) containing Memorandum (Apr. 3, 2001). from [PP Lawyer], [PP executive] and [PP executive], [PPFA-HOU_E&C-000148-000150], Exhibit 8.20.
[946] *Id.*
[947] *Id.*
[948] *Id.*

> occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.[949]

Affiliates were reminded that the accreditation reviews conducted by PPFA would hold the affiliates accountable for compliance with the memorandum:

> PPFA accreditation reviews will confirm, in the same way as for any other Medical Standard, that one of these two methods has been employed by any affiliate that chooses to participate in an aborted pregnancy tissue donation program.[950]

Affiliate clinic chief executives were also reminded that they must comply with all state and local laws regarding fetal tissue programs:

> C. Compliance With (sic) State Laws
>
> We remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well.
>
> If you have questions about the federal statutes, feel free to call [PP Lawyer] at: . . .[951]

Ten years later, on January 26, 2011, [PP Witness #1] and [PPFA Executive] reissued the memorandum to "Affiliates CEOs, Medical Directors, and Patient Services Directors" under their names as a reminder of the importance of compliance with the MS&G and federal law.

The memorandum formed the basis for two lines of investigation undertaken by the Panel: (1) the Panel sought to obtain the background accounting documents prepared or relied upon by affiliates in forming their basis for compliance with the memorandum and federal law;[952] and (2) the Panel sought to conduct interviews with PPFA executives about compliance with the memorandum.

[PP Witness #1] participated in a transcribed interview with the Panel on October 6, 2016. Early in the interview, [PP Witness #1] explained that although her name appears on the memorandum "send line," it was sent not by her, but by a staff member of hers, [PPFA Executive]. [PP Witness #1] was asked if she supported the memorandum's guidance:

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[949] *Id.*
[950] *Id.*
[951] *Id.*
[952] *See* Letter from March T. Bell, Staff Director, House Select Investigative Panel, to K. Lee Blalack II, Esq, O'Melveny & Myers, LLP (Sept. 8, 2016) [hereinafter Blalack letter], Exhibit 8.21.

> [PP Witness #1]: As to what my opinion is, my opinion is that the affiliates need to follow the guidance that they are provided with.
>
> BY MR. BELL:
>
> Q And that would include, would it not, either getting no recovery of costs or hiring an auditor, one of those two?
>
> A That is what the guidance says.
>
> Q And you support that guidance?
>
> A That's the PPFA guidance. That's—I don't know what my other option is.[953]

The Panel found no compliance with the requirement that affiliates rely upon an auditor before entering into a fetal tissue donation program.

7. Planned Parenthood Clinics Profited from the Sale of Fetal Tissue

The Panel initially designed its investigation into the whole of the nation's fetal tissue industry as described in the "Investigative Design section" above. Later in the year, the Panel relied upon the confluence of six important factors that caused it to look into the records of individual Planned Parenthood abortion clinics that chose to participate in fetal tissue donation:

- First, many of the clinics contracted with StemExpress whose marketing materials offered a profit to clinics who allowed it "plug-in" tissue procurement program in their clinics.[954]

- Second, The CMP undercover videos revealed a "wink and a nod" attitude by PPFA executives who seemed to communicate that fetal tissue programs help with revenue but don't get caught because the headlines would be a disaster.

- Third, the economic environment of the clinics seemed conducive to measures that would improve revenue.

- Fourth, the Panel's hearing on *The Pricing of Fetal Tissue*, sought the judgment of seasoned federal prosecutors to compare the federal statute prohibiting profit from fetal tissue sales with the first tranche of materials from the investigation. Two former U.S. attorneys and a senior federal litigator agreed that, based on the materials presented to them, they would open a case against a middleman company. The former prosecutors also suggested that accounting and bank records would be critical to understanding

[953] Transcribed Interview of [PP Witness #1] at 32 (Oct. 6, 2016).
[954] StemExpress Brochure [NAF 000001-000002-Brochure.pdf], Exhibit 8.22

whether there was a violation of federal law. Minority witnesses agreed with this approach and urged the panel to obtain such records.

- Fifth, the production from StemExpress and their bank revealed substantial payments to Planned Parenthood affiliate clinics.

- Sixth, interviews with [StemExpress founder and CEO] revealed that the staff of StemExpress was performing all the tasks in the Planned Parenthood affiliates clinics required for procuring fetal tissue.

8. The Panel Investigates Planned Parenthood Affiliate Clinics

PPFA and their affiliate abortion clinics agreed to cooperate voluntarily with the Panel's investigation. PPFA had produced several costs estimates to the House Energy and Commerce's Oversight and Investigations Subcommittee that reported that PP affiliates lost money participating in fetal tissue donation:

> PP Los Angeles—$1,065.65 loss on $15,750.00 in fetal tissue revenues;
> PP Mar Monte—$2,209.32 loss on $18,955.00 in fetal tissue revenue;
> PP of Northern California—$830.64 loss on $1373.00 fetal tissue revenue;
> PP Pacific Southwest—$18,670.84 loss on $18,960.00 in fetal tissue revenue[955]

Thus, the Panel delivered a document request to PPFA's counsel that listed detailed requests for accounting support documents that formed the basis for the materials produced by each clinic.[956] The Panel sought to rely upon a forensic accounting analysis to verify whether these cost estimates were reasonable,[957] accurate, and whether they were allowable under 42 U.S.C. §§ 289g-2(a) and (e)(3). A complete review of the PPFA production produced an incomplete picture. First, the cost analysis and revenue materials produced by PPFA were for 2015, a year in which PPFA decided to stop taking payments for fetal tissue. Second, PPFA produced no background accounting documents to support its cost claims. Third, the Planned Parenthood affiliate cost claims were on their face ambiguous because they assigned costs to the Planned Parenthood affiliate that were clearly paid by the contracted middleman tissue company. Thus, on November 14, 2016, the Panel wrote a further document request to obtain genuine accounting documents.[958]

The Planned Parenthood affiliate clinic cost estimates were analyzed under the rubric of longstanding federal law. On March 10, 1993, the House debated two competing amendments to H.R. 4, the National Institutes of Health Revitalization Act of 1993. The amendments, one offered by Rep. Bliley and one by Rep. Waxman, focused on safeguards governing the donation

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[955] Planned Parenthood Fetal Tissue Expenses Chart, [PPLA-HOU_E&C-0000019, PPMM-HOU_E&C-000002, PPNC-HOU_E&C-000002, PPPSW-HOU_E&C-000002], Exhibit 8.23.
[956] Blalack letter, Exhibit 8.21.
[957] Planned Parenthood Fetal Tissue Expenses Chart, Exhibit 8.23.
[958] Letter from March T. Bell, Staff Director, House Select Investigative Panel, to K. Lee Blalack II, O'Melveny & Myers, LLP (Nov. 14, 2016), Exhibit 8.24.

of fetal tissue for transplantation and for research. The House passed the Waxman Amendment to H.R. 4, the National Institutes of Health Revitalization Act of 1993. That Amendment includes the provisions codified as 42 U.S.C. §§ 289g-2(a) and (e)(3):

- 42 U.S.C. § 289g-2(a) states, "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

- 42 U.S.C. § 289g-2(e)(3) adds, "The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

During floor debate, supporters of the Waxman Amendment repeated over and over that "fetal tissue may not be sold."[959] Rep. Morella expressed her support for the legislation because "fetal tissue could not be sold."[960] Rep. Waxman himself said:

> This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any purpose, just not for the purpose of research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.[961]

The floor debate corroborates the Committee Report language. The Report from the Committee on Energy and Commerce stated, "Section 498B prohibits the purchase of human fetal tissue as well as the solicitation or acceptance of directed fetal tissue donations."[962] The Committee prohibition on the sale of fetal tissue is described as making the transfer of fetal tissue parallel with donation of other organs under the Organ Procurement and Transplantation Act.[963] The Committee Report adds, however, "Indeed the Committee has dealt with fetal tissue more restrictively . . . ."[964] The Committee intent is to disallow payment for procurement of any organs.

The intent of the statute is best understood through a simple contrast between two modes of transferring fetal tissue from one entity to another. With the first, an abortion clinic or middleman procurement business transfers tissue to a researcher, and the researcher may reimburse the abortion clinic or procurement business for its reasonable costs incurred by the transportation, processing, preservation, and quality control of the tissue. With the second, the payment from the researcher exceeds those reasonable costs, enabling the abortion clinic or procurement business to make a profit and thus violate the statute.

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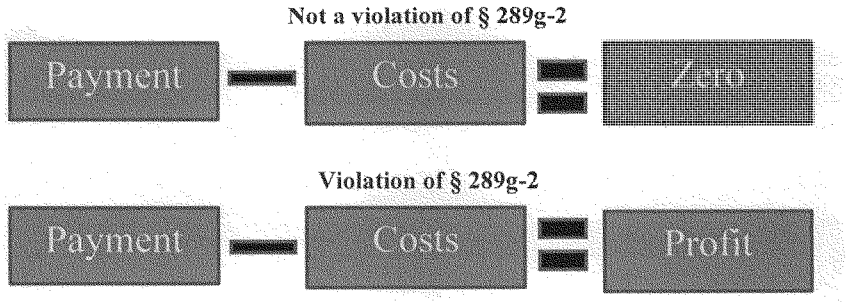
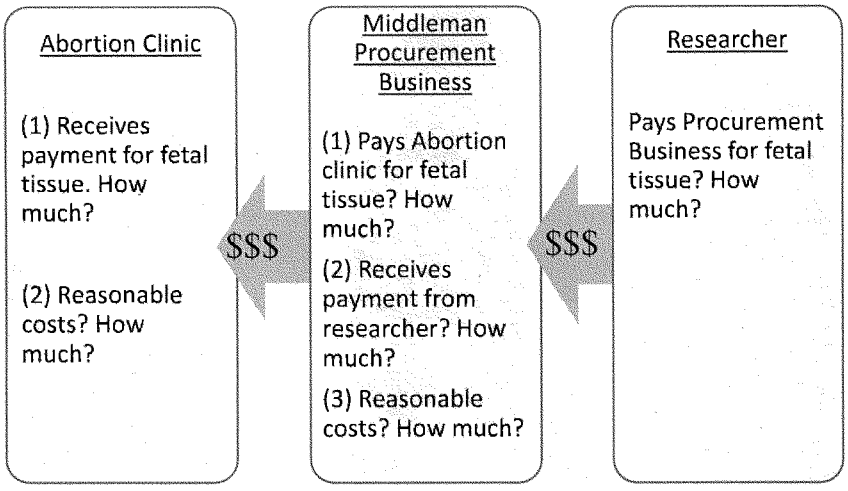
[959] 139 Cong. Rec. H1099 (1993) (statement of Rep. John Edward Porter in support of the Waxman Amendment).
[960] 139 Cong. Rec. H1099 (1993) (statement of Rep. Connie Morella in support of H.R. 4 and the Waxman Amendment).
[961] 139 Cong. Rec. H1099 (1993) (statement of Rep. Henry Waxman).
[962] H.R. Rep. No. 103-28 at 76 (1993).
[963] Pub. L. No. 98-507, 98 Stat. 2339 (1984).
[964] H.R. Rep. No. 103-28 at 76 (1993).



The congressional intent of the Waxman Amendment served as a guide for the Panel's investigative plan of the Planned Parenthood affiliate clinics. The core question became the following: If fetal tissue is transferred from one entity to another, does the transfer violate the intent of § 289g-2? To answer this question, the panel identified four business models currently operating in the market sector and one operating in the public sector. The *Middleman Model* comprises a middleman tissue procurer who obtains tissue directly from a source such as a PPFA affiliate clinic and then transfers the tissue to a customer, usually a university researcher.

The Panel started its inquiry into the middleman or tissue broker model, the primary business model for the transfer of human fetal tissue. The statute raises several fundamental questions about this model as displayed by the graphic below.


Abortion Clinic
(1) Receives payment for fetal tissue. How much?
(2) Reasonable costs? How much?
$$$
Middleman Procurement Business
(1) Pays Abortion clinic for fetal tissue? How much?
(2) Receives payment from researcher? How much?
(3) Reasonable costs? How much?
$$$
Researcher
Pays Procurement Business for fetal tissue? How much?

The middleman investigation, and in particular the investigation of StemExpress, produced information about several PPFA affiliate clinics.[965] In particular, it became clear that StemExpress was doing all the work to obtain consent for donation from individual patients, that StemExpress was doing the work of harvesting the fetal tissue after an abortion was complete, and that StemExpress was doing the work and passing on its costs of shipping to customers. This raised a profound issue for the Panel: Both the middleman and the PPFA affiliate clinic were claiming the same expenses against their revenue to show a loss on fetal tissue sales.

9. PPFA Affiliates and StemExpress Claim the Same Expenses

Attorneys for StemExpress created several cost estimates that purport to show that StemExpress loses money each time it procures a fetal tissue sample and ships it to a customer. These are graphically summarized in the column with orange numbers in the chart below.

COMPARISON OF STEMEXPRESS COST ANALYSIS WITH GENERALLY ACCEPTED INDUSTRY STANDARDS FOR ONE UNIT OF FETAL TISSUE IN 2013

COST ITEMS AND ESTIMATE PRODUCED BY STEMEXPRESS

ADJUSTED BASED ON REASONABLE INDUSTRY STANDARDS

COSTS ALLOCATED TO MATERNAL BLOOD ESTIMATED AT 50%

Cost Item	Description	Estimated Time	Estimated Cost/Expense	[illegible]	[illegible]	% Costs for Maternal Blood
Procurement Management Labor	Receive and evaluate purchase order, enter into Computer system and task board, assign to clinics.	1 hour x $35	$25.00	[illegible]	[illegible]	[illegible]
Packaging Supplies Labor	Packaging all supplies needed for procurement.	1 hour x $10	$10.00	[illegible]	[illegible]	[illegible]
Shipping	Supplies to Clinic	N/A	$15.00		$15.00	$7.50
Mileage	Mileage paid to technician (.56/mile)	N/A	$75.00		$75.00	$35.00
Supply cost	Box, conical tube, media, petri dish, labels, biohazard bag, gel packs, etc.	N/A	$30.00		$30.00	$15.00

[965] *See* Chapter V.A *supra*.

Technician Base Labor	Patient consent, procurement, paperwork packaging.	8 hour x $10	$80.00	1 hour x $10	$10.00	$5.00
Technician Supplemental Compensation	Technician Supplemental Compensation	N/A	$30.00		$0.00	$0.00
Clinic Reimbursement	Technician space, storage of supplies, blood draw chair usage, consent space	N/A	$55.00		$55.00	$27.50
Infectious Disease Draw	Supplies: tubes, labels, needle, biohazard bag, etc.	N/A	$15.00		$15.00	$7.50
Infectious Disease Screening	Screening for HIV, HepB, HepC, LCMV	N/A	$70.00		$70.00	$35.00
Shipping	Average Shipment cost to the Lab (blood and/or tissue)	N/A	$20.00		$20.00	$10.00
Procurement Management Labor	Review paperwork, communications with courier, communications with researcher	1 hour x $35	$35.00		$35.00	$5.00
Product Receipt	Receipt of product at front desk, check into Sage, check into log	1 hour x $15	$15.00	.25 hour x $15	$4.00	$2.00
Inventory & Supply Management	Prorated stores management	1 hour x $20	$20.00	.25 hour x $20	$5.00	$2.50
			$495.00		$351.50	175.75

Shown in orange, the cost estimates produced by the attorneys are inconsistent with accounting records produced by StemExpress itself. For example, StemExpress lists clinic reimbursement defined as "Technician space, storage of supplies, blood draw chair usage, consent space" which the Panel found was **not** an actual payment made by StemExpress to the clinics. Also, the costs associated with shipping and infectious disease are passed on to the customer and thus are **not** a cost to StemExpress. Finally, management labor costs at one hour per item ordered, which are counted twice, are dramatically inconsistent with the number of orders actually handled by StemExpress. Similarly, StemExpress estimates do **not** allocate any costs (such as mileage) to maternal blood which is harvested at the abortion clinic at the same time the human fetal tissue is harvested.

StemExpress has consistently refused to produce subpoenaed accounting documents that the Panel requires to complete its analysis. In the summary below, StemExpress claimed as expenses various items that were reimbursed by customers. Our forensic accounting analysis revealed that if these reimbursements were accounted for, they would yield a profit to StemExpress.

Sample review of a sale of maternal blood to customer Baylor per invoice #1940 of 1/12/2013	
Sale price for Tissue	$250.00
Disease screening charged to client	$125.00
Shipping charged to client	$85.00
Total Revenue obtained from this sale	$460.00
Estimated cost of Tissue (per above)	$175.75

Sample review of a sale of fetal tissue to customer Baylor per invoice #1940 of 1/12/2013	
Sale price for Tissue	$250.00
Disease screening charged to client	$125.00
Shipping charged to client	$85.00
Total Revenue obtained from this sale	$460.00
Estimated cost of Tissue (per above)	$351.00
Excess of revenue over cost	$108.50

StemExpress and other productions reveal that the payments to Planned Parenthood affiliates are for each item of fetal tissue.[966] The graphic below summarizes the known payments to various Planned Parenthood clinics for fetal tissue.

Procurement Business	Planned Parenthood Clinic	2010	2011	2012	2013	2014	2015	Total
ABR	First Avenue	52,075	36,000	20,400	18,600	18,240	-	**145,315**
	Mar Monte	5,390	-	-	-	-	-	**5,390**
	Riverside	16,020	21,660	36,720	33,540	31,740	23,460	**163,140**
	Pacific Southwest	-	-	-	-	-	18,960	**18,960**
	San Diego	-	-	-	-	-	13,080	**13,080**
	San Jose	5,500	-	-	-	-	-	**5,500**
Stem Express	Mar Monte	2,910	48,388	74,625	40,220	40,630	18,955	**225,728**
	Shasta Pacific	-	-	2,520	8,340	8,690	1,375	**20,925**
Novogenix	Los Angeles	-	-	-	-	-	15,750	**15,750**
		81,895	**106,048**	**134,265**	**100,700**	**99,300**	**91,580**	**613,788**

10. Planned Parenthood Production Schedule of their Costs Associated with Fetal Tissue Donation

Deductions from the revenue summarized above were described in Planned Parenthood affiliates' cost estimates produced to the House Committee on Energy and Commerce to each show a net loss resulting from their participation in fetal tissue donation for research. Section 289g-2 makes certain costs associated with fetal tissue allowable as a deduction from and

[966] See StemExpress contracts with PP Mar Monte, PP Shasta Pacific and PP Santa Barbara, [Stem.House.OGR-_000001-6 and 000015-17/Stem.House.Select_0167-172 and 0181-0183], Exhibit 8.25.

valuable consideration received for the tissue. The Panel sought to investigate and analyze these costs from several perspectives:

1) Did the affiliate rely upon an auditor to create a framework for allowing costs?

2) Did PPFA executives take seriously the statute's requirement that profiting from the sale of fetal tissue is a Section 289g-2 violation?

3) Did any middleman organization provide services to the affiliate or claim expenses that would disqualify costs claimed by the affiliate?

4) Are the affiliate-listed costs allowable under the limitations of Section 289g-2?

5) Did the affiliate include job descriptions of its employees for which it listed costs?

Costs Listed by Planned Parenthood Affiliates

Four affiliates provided schedules listing cost and revenue for a one-year time period (FY 2015). These schedules are listed below.[967]

Planned Parenthood Los Angeles

Listed costs:	$16,815.65
Reimbursements:	$15,750.00
Net Loss:	($1,065.65)

Planned Parenthood Mar Monte

Listed costs:	$21,245.32
Reimbursements:	$18,955.00
Net Loss:	($2,209.32)

Planned Parenthood Northern California

Listed costs:	$16,815.65
Reimbursements:	$15,750.00
Net Loss:	($830.64)

[967] Planned Parenthood Fetal Tissue Expenses Chart, Exhibit 8.23.

Planned Parenthood Pacific Southwest

Listed costs:	$16,815.65
Reimbursements:	$15,750.00
Net Loss:	($18,670.84)

11. The Planned Parenthood Cost Documents Are Unsupported

In the transmittal letter to the Committee on Energy and Commerce dated November 10, 2015, that included the PPFA affiliate fetal tissue cost estimates, the Counsel for PPFA explains that these are estimates only:

> The affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation, and have demonstrated conclusively that those costs exceeded the payments they received. Your September 30 Letters separately request that the affiliates provide to the Committee all audits conducted of the fetal tissue donation programs, along with documents, such as calculation sheets and budgets, relating to the reimbursements they received. We have determined that these four affiliates either did not conduct or cannot locate contemporaneous cost analyses, or secure independent audit opinions as articulated by PPFA's then-existing guidance.[968]

This representation is consistent with the non-production of such documents requested a year later by the Panel. In fact, the Planned Parenthood affiliate costs requests are riddled with flaws. And they are inconsistent with the statements of PPFA's own employees. In an interview with [PP Doctor #1],[969] Committee on Energy and Commerce staff asked her about the history of contracting with Novogenix, a tissue procurement middleman. The memorandum described above in Section 5 was in effect at the time, so the staff wanted to know whether an auditor was consulted when evaluating the per specimen payment from Novogenix:

> In 2010—understanding was she received in and was aware of it [the MS&G] floating around in head, with updates; recall consulted protocol in 2010-**did not use independent auditor, did informal rough calculation of cost.**[970]

The Panel interviewed [PP Witness #2] on October 19, 2016. The interview focused on a contractual arrangement between Planned Parenthood Gulf Coast and the University of Texas Medical Branch which called for the Planned Parenthood affiliate to provide fetal tissue to the

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[968] Letter from K. Lee Blalack II, O'Melveny & Myers LLP, to the Hon. Fred Upton, the Hon. Timothy Murphy, and the Hon. Joseph Pitts (November 10, 2015) at 3, Exhibit 8.26.
[969] [PP Doctor #1] Briefing (Sept. 18, 2015), Exhibit 8.16.
[970] *Id.* at 4 (emphasis added).

medical school. [PP Witness #2] was asked how she arrived at the costs related to how much to charge the medical school:

> Q Have you seen this agreement ever before?
>
> A I have.
>
> Q And is this the type of thing that you would participate in the development of?
>
> A I have.
>
> Q Okay. So the question—one of the questions that we have is, when you decided staff time for consent [$]50, sterile [$]100, did you do—how did you come up with those numbers?
>
> A They were basically **back-of-the-envelope-type calculations** involving the time it takes staff to conduct those procedures relative to the study.[971]

[PP Witness #1] also was asked a series of questions about StemExpress making a profit in its contractual collaboration with PP affiliates. The questions were focused on the markup of an intact fetal brain from $55 paid to the Planned Parenthood affiliate versus the $3,340 charged to the customer:

> Q Three thousand three hundred and forty. Now, that—that particular brain is shipped—is shipped out of the clinic.
>
> Now, here's the scenario, and we'll be done. Tissue tech learns who's available for contributing. She goes and gets the consent. She gets paid a bonus. The Planned Parenthood clinic, I believe, gets $55, but it's in the range of [$]30 to [$]100, and StemExpress resells that brain for over $3,000.
>
> And you'll notice—you may notice on there [the invoice] that the shipping and maybe some other things are paid for by the customer.
>
> Now, does that bother you?
>
> A No.
>
> Q Okay. So if StemExpress made a profit by marking up what they paid for the tissue 2,800 percent, would that bother you?
>
> A I don't know that they're ma[r]king [sic] it up. I have no idea what their costs are.

[971] Transcribed Interview of [PP Witness #2] at 26-27 (Oct. 19, 2016) (emphasis added), Exhibit 8.27.

Q Well, if they—if it was a profit would it bother you?

A It's really none of my business, no.

Q It's not your business what StemExpress does, but how is not your business when StemExpress does this work inside of Planned Parenthood Federation clinic?

They offer a profitable situation of the clinic. They get the consent. They get the tissue, and they resell it, and you're in a contractual relationship with them. They're a vendor of Planned Parenthood. If it was a profit of 2,800 percent, would that raise a red flag for you as an organization? . . .

Mr. Bell. What I'm trying to understand, counsel, is the management mindset of a senior manager at Planned Parenthood who may or may not have seen this error before today and may or may not have known how the consent works or how the tissue tech is paid or what StemExpress marks up the tissue for.

I'm saying as the senior manager of Planned Parenthood that oversees her scope of work, is it a concern—so when they're in a contractual relationship—is making what looks like a huge profit on selling fetal tissue.

[PP Witness #1]. So the first thing that I want to just correct is you said that they were offering a profitable service or something to our affiliates, which they're not. Our affiliates don't make a profit on tissue donation.

Mr. Bell. But I just –

[PP Witness #1] I just wanted to correct that statement.

Mr. Bell. I think you're right to correct that. My concern, my question to you, Doctor, is not to reach a factual conclusion. You're one of the top people in this organization. What I want to learn is are you concerned when an organization comes to your organization and offers a profit to them, which seems to violate the guidance in the legal memo that we read earlier.

BY MR. BELL:

Q Is that a concern to you?

They come in and say, "I know you're not supposed to make a profit, but partner with us because it'll be profitable.". . .

> Mr. Bell. And here's a more granular example. It looks like StemExpress, who for several years only did abortion clinics, now they do lots of stuff, lots of other stuff. But for several years of their life they only got tissue from Mar Monte, Shasta Pacific, and resold it at prices like this.
>
> And I just want to know what's sort of the global management perspective of a Planned Parenthood senior leader like you if that's a 2,800 percent profit.
>
> BY MR. BELL:
>
> Q Would that bother you?
>
> A So just so that I'm clear on the question you're asking me if it bothers me that StemExpress makes money reselling the tissue?
>
> Q Yeah.
>
> A It's none of my concern. It doesn't bother me.[972]

In an undercover video, [PP Witness #4] told journalists that [PP Lawyer], of PPFA's legal department, had warned them about the federal laws surrounding fetal tissue donation:

> Buyer: Yeah. And as far as the specifics of remuneration, is there any guidance from [PP Lawyer] other than how to—because one thing we've talked about with [PP Witness #1] before is just to make sure that's kind of back-ended in the right way so that it's a reasonable covering—
>
> [PP Witness #4]: Yes he gave very clear instructions, that the federal law says you cannot be remunerated for tissue, what you can be remunerated for is costs of collection. So if there's admin costs, extra staff time, transport fees, materials or supplies, you just need to really document what those are, and say, you know, "This is $100 worth of whatever, or $50 worth of, admin time, materials that it's costing us." So that if somebody comes in and says, "You're collecting money for tissue," we'll say, "No we're not, we're collecting money for administrative costs." So he gave them 4 or 5 things that they should consider. So he was very clear about that.[973]

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[972] Transcribed Interview of [PP Witness #1] at 156-59 (Oct. 6, 2016), Exhibit 8.28.
[973] Center for Medical Progress, Transcript of Meeting with [PP Witness #4] at 16 (March 18, 2015), Exhibit 8.29.

12. Comparison of Costs Claimed by Planned Parenthood Affiliates and Expenses Claimed by Fetal Tissue Middleman StemExpress

The Panel took note of both StemExpress and the Planned Parenthood clinics listing the same expenses as costs against their revenue for fetal tissue transfers. In StemExpress' case, they list costs paid by the customer, but both StemExpress and Planned Parenthood list the same costs in their production to the Panel. This comparison is described in the graphic chart below.

StemExpress vs. Planned Parenthood

Cost Deduction Chart[974]

	Claimed By		
Cost Type	**Planned Parenthood**	**StemExpress**	**Comments: PP vs. SE**
Supplies	(Mar Monte) Y	Y	"Supplies/Equipment" for tissue collection and consent vs. "Supplies to clinics" and "supply costs"
Consent	(Mar Monte) Y	Y	"Staff time interpreting... verifying and signing...scanning" consent forms" vs. "patient consent," and "consent space"
Handling supplies	(Mar Monte) Y	Y	"Staff Time cleaning Stem Express Equipment" vs. "Storage of supplies"
Shipping supplies	(Mar Monte) Y	Y	"Shipping labels" vs. "packaging all supplies needed for procurement" and "Shipment to lab"
Work space	(Mar Monte) Y	Y	"Use of Space by StemExpress Representatives" vs. "technician space" and "consent space"

[974] Planned Parenthood Mar Monte and Shasta Pacific Fetal Tissue Costs [PPMM-HOU_E&C-000001-02, PPNC-HOU_E&C-000001-2], Exhibit 8.23.

Consent	(Shasta-Diablo) Y	Y	"Costs associated with obtaining patient consent...Staff time verifying and signing...scanning" consent forms" vs. "patient consent," and "consent space."
Tech Transportation	(Shasta-Diablo) Y	Y	"Costs associated with transportation...tubing for Sterile Instrument Transportation" vs. "packaging all supplies needed for procurement" and "Shipment to lab"
Tissue screening	(Shasta-Diablo) Y	Y	"Staff Time screening donated tissue" vs. "Screening for HIV, HepB, HepC, LCMV"
Work Space	(Shasta-Diablo) Y	Y	"Use of Space by StemExpress Representatives: Dedicated work areas and Storage areas" vs. "technician space" and "consent space"

The chart above illustrates how two Planned Parenthood clinics and a middleman company, StemExpress, both claimed expenses for the same costs. This "double counting" found by the Panel's forensic accounting analysis raised serious doubts about whether the affiliates' estimates were anything more the "back of the envelope" guesses. The timing of the creation also raises the question whether the cost estimates were created for public advocacy purposes.

13. Planned Parenthood Affiliates' Cost Schedules Compared to the Defined Allowable Costs in 42 U.S.C. § 289g-2

The Panel noted that the language describing "allowable costs" under Section 289g-2 are costs associated with activities that are downstream from the tissue procurement process that takes place inside an abortion clinic with the exception of "transportation." In virtually every example examined by the Panel, "transportation" was a cost passed on to the end user or customer, usually a university researcher.

- Since Section 289g was passed by Congress at a time when the state of biomedical research anticipated that fetal tissue would be transplanted into human subjects, the statute allows costs associated with *"implantation."* Since implantation does not occur at the abortion clinic level, it is unreasonable that any costs counted against payments for fetal tissue could be claimed by either a clinic or by a middleman tissue procurer.

- *Processing* of fetal tissue occurs in two places: (1) some middleman companies "process" fetal tissue into concentrated cell lines for specific research applications or the end user processes the tissue into a cell line or other research tool such as a humanized mouse. Thus, processing by definition cannot take place at the Planned Parenthood affiliate clinic.

- *Preservation* refers to one of several methods whereby recently harvested fetal tissue is stabilized so the cell properties will not deteriorate. This could be immediate refrigeration (possible cost to an affiliate clinic), placing the tissue in a serum such as a bovine calf serum for stabilization and shipment, or simply placing the tissue in packaging with an ice pack for shipping. Other preservation would be undertaken by the end user at the time of receipt.

- *Quality control* is similarly not the province of the abortion clinic. The remains of an unborn child are caught in a nominally sterile pan. A tissue technician sorts through the remains and harvests the tissue for which she has customer orders. In virtually all cases, the tissue is packaged immediately for shipping. This work is usually performed in a clinic pathology lab which exists to make sure all body parts are removed from the mother's uterus and then the remains are stored for disposal. There is no quality control performed by the abortion clinic at this point in the fetal tissue procurement process. Quality control refers instead to the downstream effort by the researcher to assure the purity and integrity of their specimen, anticipated at the time of passage of § 289g to be transplant into a human subject.

- *Storage* is a possible cost to an affiliate clinic if it allowed harvested tissue or partial baby cadavers to be stored by refrigeration. No Planned Parenthood clinic reported that it acquired additional refrigeration capacity as a result of participation in a fetal tissue donation project.

The locus of most storage costs would be again by the downstream end user, a researcher who may store a cell concentration or even frozen fetal tissue for months or years.

The chart below reveals that the claimed cost schedules produced by Planned Parenthood actually attempt to allocate costs to the clinics that are more properly assigned to the middleman procurer or the end user researcher.

Planned Parenthood Costs Compared to Allowable Reimbursements Under 42 U.S.C. § 289g-2

Planned Parenthood Affiliates Claimed Costs	**Transportation**	**Implantation**	**Processing**	**Preservation**	**Quality Control**	**Storage**
Planned Parenthood Mar Monte/SE						
Staff Time Coordinating and Managing Patient Flow	NO	NO	NO	NO	NO	NO
Staff Time Supervising / Coordinating with Stem Express Representative	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Interpreting Consent Forms	NO	NO	NO	NO	NO	NO
Staff Time Verifying and	NO	NO	NO	NO	NO	NO

Signing Consent Forms						
Staff Time Scanning Consent Forms	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Cleaning Stem Express Equipment	NO	NO	NO	NO	NO	NO
Staff Time Invoicing Stem Express	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Use of Space by Stem Express Representatives	NO	NO	NO	POSSIBLY	NO	NO

Staff Time Supervising / Coordinating with Stem Express Representative	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
Planned Parenthood Shasta Pacific						
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Verifying and Signing Consent Forms	NO	NO	NO	NO	NO	NO
Staff Time Scanning Consent Forms	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Coordinating Courier Service for Stem	POSSIBLY	NO	NO	NO	NO	NO

Express Representative						
Staff Time Screening Donated Tissue	POSSIBLY	NO	NO	NO	NO	NO
Staff Time Invoicing Stem Express and Coordinating Program	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Use of Space by Stem Express Representatives	NO	NO	NO	POSSIBLY	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Planned Parenthood Mar Monte/ABR						
Staff Time Communicating with ABR	NO	NO	NO	NO	NO	NO

Representative Prior to Collection						
Staff Time Supervising / Coordinating with ABR Representative	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Discussing Program with Patients, Obtaining Consent or Declination	NO	NO	NO	NO	NO	NO
Staff Time Preparing Consent Forms, Whiteboard, and Anonymized Consent List	NO	NO	NO	NO	NO	NO
Staff Time Sending Consent Forms to Administrative Office	NO	NO	NO	NO	NO	NO

Supplies / Equipment	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Extra Tissue Examination Time	POSSIBLY	NO	NO	NO	NO	NO
Staff Time Transferring Tissue to ABR Representative	NO	NO	NO	NO	NO	NO
Staff Time Managing Deliveries, Moving Boxes, & Discarding Documents for ABR Representative	POSSIBLY	NO	NO	NO	NO	NO
Staff Time Coordinating Courier Service for ABR Representative	POSSIBLY	NO	NO	NO	NO	NO
Staff Time Invoicing ABR Reimbursement	NO	NO	NO	NO	NO	NO
Staff Time Installing Shelf for ABR Representative	NO	NO	NO	NO	NO	NO

Supplies / Equipment	NO	NO	NO	NO	NO	NO
General Administrative Overhead	NO	NO	NO	NO	NO	NO
Use of Space by ABR Representatives	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Planned Parenthood Los Angeles						
Staff Time Preparing Surgical List and Internal Coordination	NO	NO	NO	NO	NO	NO
Staff Time Coordinating with Novogenix Representative	NO	NO	NO	NO	NO	NO
Staff Time Attending Morning Meetings' Discussion of Donation Program	NO	NO	NO	NO	NO	NO
Staff Time Managing and	NO	NO	NO	NO	NO	NO

Overseeing Tissue Donation Program						
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Management & General Overhead	NO	NO	NO	NO	NO	NO
Staff Time Discussing Program with Patients, Obtaining Consent or Declination	NO	NO	NO	NO	NO	NO
Staff Time Preparing, Processing, and Photocopying Consent Forms	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Management & General Overhead	NO	NO	NO	NO	NO	NO
Staff Time Transferring Tissue to Novogenix Representative	POSSIBLY	NO	NO	NO	NO	NO

Staff Time Disposing of Unused Tissue	NO	NO	NO	NO	NO	NO
Staff Time Coordinating with Novogenix Representative	NO	NO	NO	NO	NO	NO
Staff Time Invoicing Novogenix Reimbursement	NO	NO	NO	NO	NO	NO
Staff Time Revising Electronic Health Records	NO	NO	NO	NO	NO	NO
Management & General Overhead	NO	NO	NO	NO	NO	NO
Use of Space by Novogenix Representatives	NO	NO	NO	POSSIBLY	NO	NO
Management & General Overhead	NO	NO	NO	NO	NO	NO

14. Job Descriptions of Planned Parenthood Staff ***do not*** Include any Reference to Tasks or Responsibilities Associated with Fetal Tissue

After reviewing the cost schedules of Planned Parenthood affiliates, the Panel requested and obtained job descriptions from the counsel representing the entities. The Panel sought to determine whether job descriptions or job announcements included any reference to tasks related to fetal tissue donation. The Panel similarly sought any information that the affiliates' participation in fetal tissue donation required the hiring of new staff. The Planned Parenthood affiliates produced no evidence to support either job description adjustments or hiring of new employees due to the tasks involved in any aspect of fetal tissue donation. The chart below summarizes the job descriptions of the employees at the affiliates.

Review of Staff Time Claimed by Planned Parenthood as Part of Costs Associated with Collecting and Processing Fetal Tissue as Compared to Job Descriptions of Staff

Staff Title	Includes Fetal Tissue	Does Not Include Fetal Tissue
Planned Parenthood Mar Monte:		
Health Services Specialist: Provides direct service in all health centers, provides clients with accurate info regarding PP services, screens patient history, etc.		☐
Abortion Coordinator: Scheduling, notify patients of follow-ups, provide medical record transfers, serve as liaison between PPMM and outside lab to follow-upon concerns with results interpretation and transmission.		☐
Center Manager: Responsible for the day-to day management of all health center activities.		☐
Chief Medical Officer: Oversee maintenance of medical records, credentialing of staff, hire and supervise senior staff, represent PPMM on managed care plan committees, and local, state, and national task forces, committees and Boards.		☐
Clinician: Review and interpret medical/social history of patients, perform screening procedures/exams, interpret lab		☐

data, provide contraceptive methods, provide non-surgical abortion, act as medical consultant to clinic staff.		
Check-Out Specialist: Posts charges to and ensures accuracy of Electronic Practice Management system, sends CDS to billing department, handles patient check-out, calculates and collects fees, solicits contributions, schedules future appointments.		☐
Assistant Lab Manager: Match specimens to requisitions, prepare specimens for testing, notify clinics of positive results, perform/supervise laboratory testing in compliance with appropriate policies/guidelines.		☐
Accountant: Conduct analysis as needed for the purpose of verifying appropriate allocation of Accounts Payable duties, responsible for completeness and accuracy of Accounts Payable vouchers, review and reconcile vendor statements to include analyzing charges and payments. Verify and maintain all rental, lease, and contract accounts.		☐
Registered Nurse: Provide care for patients under established Medical Protocols, perform various medical procedures, administer medication, assess status of patients.		☐
Center Manager: Ensuring efficient coordination, management of workflow, efficient implementation of new services, and management of health center staff resources for services provided. Assure medical center's compliance with agency's state and federal regulations. Oversight of supervisory responsibilities in accordance with policies and applicable laws.		☐
Medical Assistant: Responsible for all supporting functions in the delivery of reproductive health care services. Assist patients by providing testing, screening,		☐

and education required for the provision of medical productive health care.		
Clinician: Provide quality patient care including exam, diagnosis, treatment, education and counseling for clients in accordance with agency protocols.		☐
Surgical Technician: Member of an operating room team during surgical and endoscopic procedures. Serves as a scrub technician in an operating room and provides direct and indirect care to patients before, during, and after surgery.		☐
Medical Director: Responsible for ensuring provision, coordination and oversight of medical services. Assumes responsibility for training, supervisor and evaluation of all clinicians in concert with medical Management Leadership.		☐
Vice President of Patient Services: Ensures the continuing provision of high quality services to all patients. Oversees laboratory services, research and training program teams and clinical compliance and risk management.		☐
Administrative Assistant for Patient Services: Provides secretarial and administrative support to the Vice President, Patient Services, Medical director, and others in the Patient Services department.		☐
Vice President of Medical Services: Responsible for the overall development, management, and supervision of clinic staff and serviees. Collaborates with other departments to provide community services. Responsible for center planning and fiscal management.		☐

Center Director: Direct oversight for the overall development, management, and supervision of center staff and services. Monitor client volume, capacity and productivity. Provide direct patient care approx. 10-20% of the time. Plan and implement new programs and services as needed.		☐
Abortion Services Coordinator: Assist with management of abortion services, assist Center Director with compliance to protocols and licensing standards, program management including audits, statistical reports, medical follow-up and maintenance of manuals.		☐
Medical Director: proposes recommendations on medical policies, reviews all medical protocols, serves as the Director of Abortion, Ultrasound, Sedation, and Colposcopy Services.		☐
Medical Services Manager: Works with VP of Medical Services and other staff in development of systems, processes, and forms to enhance efficiency at the centers, manages the proficiency testing program, manages the surgical and medication abortion reporting systems, responsible for the abortion complication reports and colposcopy correlation data systems.		☐
Planned Parenthood Pacific Southwest:		
Front Desk: Responsible for greeting and checking-in clients, preparing, scanning and coordinating paperwork, determining payer source, collecting fees/receipts and donations, collecting IDs, answering phones, scheduling.		☐
Center Manager: Manage and oversee the provision and delivery of efficient center operations and client services in a specialty services (abortion, permanent birth control, colpo/LEEP) setting, as prescribed by the Agency's protocols, policies, and procedures.		☐

Flow Coordinator: Develop and maintain a system for optimal center flow. Monitor/minimize wait times and patient/staff schedules, ensure clinicians maximize productivity by arranging patient charts to keep all rooms filled.		☐
Medical Assistant: Obtain medical history, interview and educate clients ensuring informed consent, perform options and abortion education, make appointments/referrals for follow-up services, perform PC and recovery room responsibilities, perform basic lab work.		☐

The Panel concluded that costs associated with fetal tissue transfer, an important activity that requires permission from PPFA, is governed by PPFA guidance, and is not included in any job description, sullies the credibility of a claim that actual costs are associated with the duties of relevant employees.

F. Changing the Method of Abortion Procedure to Obtain More Fetal Tissue

The Panel investigated the possible impact on clinical medical care when a fetal tissue procurement company enters into a contract to procure fetal tissue with a Planned Parenthood affiliate clinic. The middleman company often embeds a tissue technician in a clinic on the days that abortions are performed. The procurement company pays the clinic on a per tissue basis. The number of saleable body parts in many ways depends upon the methodology of the doctor performing the abortion.

Current federal law forbids changing of the method of abortion for the purpose of obtaining tissue, but this prohibition applies only to fetal tissue that is to be used for transplant purposes. The Panel noted the scope of the statute but also learned that in virtually every instance, the doctor performing the abortion had no knowledge of whether the tissue was destined for research or transplantation.

One Panel witness, Dr. Goldstein, was in fact procuring brain tissue from a Planned Parenthood affiliate clinic and using it for transplant purposes.[975] Thus, the Panel sought to determine: (1) whether there was evidence that doctors changed the abortion procedure to serve the goal of fetal tissue donation; and (2) whether particular doctors met with or learned from the contracted embedded tissue technicians about what body parts they were procuring that day in a way that promoted altered abortion procedures.

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[975] "We use fetal astrocytes, which are vital to these investigations. . . . Now, as a result of the work in animals, we have FDA approval to test these fetal stem cells in human patients . . . and have implanted them in four patients within the past year." *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 149 (unedited transcript) (Mar. 2, 2016) (Testimony of Lawrence Goldstein, at 109-111), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.

Of additional concern to the Panel was the large number of intact calveriums (skulls) that were being purchased by researchers. Since most second trimester abortions are D&E procedures, the life of the baby is terminated inside the womb through dismemberment of the various body parts. The challenge for procurement of the calverium is its size relative to the amount of cervical dilatation. This inquiry took place during interviews with practicing abortion doctors and relied upon the initial evidence from the CMP undercover videotapes.

1. Changing the Presentation of the Baby to Harvest a Calverium

In one section of a CMP video transcript, the undercover journalist (Buyer) is talking with [PP Witness #1]:

> Buyer: Yeah. Or especially brain is where it's actually a big issue, hemispheres need to be intact, it's a big deal with neural tissue and the progenitors, because those are particularly fragile. If you've got that in the back of your mind, if you're aware of that, technically, how much of a difference can that actually make if you know kind of what's expected or what we need, versus—
>
> [PP Witness #1]: **It makes a huge difference. I'd say a lot of people want liver. And for that reason, most providers will do this case under ultrasound guidance, so they'll know where they're putting their forceps. The kind of rate-limiting step of the procedure is the calvarium, the head is basically the biggest part. Most of the other stuff can come out intact. It's very rare to have a patient that doesn't have enough dilation to evacuate all the other parts intact.**
>
> Buyer: **To bring the body cavity out intact and all that?**
>
> [PP Witness #1]: **Exactly. So then you're just kind of cognizant of where you put your graspers, you try to intentionally go above and below the thorax, so that, you know, we've been very good at getting heart, lung, liver, because we know that, so I'm not gonna crush that part, I'm going to basically crush below, I'm gonna crush above, and I'm gonna see if I can get it all intact. And with the calvarium, in general, some people will actually try to change the presentation so that it's not vertex, because when it's vertex presentation, you never have enough dilation at the beginning of the case, unless you have real, huge amount of dilation to deliver an intact calvarium. So if you do it starting from the breech presentation, there's dilation that happens as the case goes on, and often, the last, you can evacuate an intact**

> **calvarium at the end. So I mean there are certainly steps that can be taken to try to ensure—**
>
> Buyer: **So they can convert to breach, for example, at the start of the—"**
>
> [PP Witness #1]: **Exactly, exactly. Under ultrasound guidance, they can just change the presentation.**
>
> Buyer: Okay.
>
> [PP Witness #1]: So the preparation would be exactly the same, it's just the order of the removal of the products is different. And most people see that as not very—
>
> Buyer: Yea, we're not talking about it needs to be a hysterotomy or anything, or something crazy like that, in order to—there's probably an easier solution to this problem.
>
> [PP Witness #1]: And, we've been pretty successful with that. I'd say.[976]

Thus, the Panel sought to investigate instances of "medically unnecessary" changes to the abortion procedure to obtain fetal tissue for transfer to a customer. In particular, the Panel noted that if the tissue technician was seeking an intact calvarium, the doctor would use an ultrasound to turn the baby to a breech position and then dismember the limbs and torso first so that greater dilation could occur and increase the likelihood that when the time came to remove the calvarium there might be greater dilatation.

This was not the only recounting by [PP Witness #1] of changing the method of abortion to obtain an intact calvarium:

[PP Witness #1]: I let the tech tell me what it is that they need, I usually don't let the trainee do those cases, **I try to do everything as intact as possible, because I know it's a research case.** She seems to be getting what she needs. **Sometimes she'll tell me she needs brain, and we'll leave the calvarium until last, and then try to basically take it, or, actually, you know, catch everything and even keep it separate from the rest of the tissue, so it doesn't get lost.** There will probably be providers who just want to keep

[976] Center for Medical Progress, Transcript of Meeting with Senior Director, Medical Services, Planned Parenthood of America at 11-12 (July 25, 2014), Exhibit 8.30.

> doing things the way that they do them, and others who kind of want to help facilitate the process.[977]

2. Abortion Doctor and Contract Tissue Technician Communicate Prior to the Abortion Procedure

The Panel sought to learn whether contact between the embedded tissue technician and the abortion doctor would lead to modification of the abortion procedure. This issue was raised in the following undercover CMP video:

> Buyer: **So yesterday was a clinic day. So for example, what did you procure?**
>
> [PP Witness #1]: **You know I asked her at the beginning of the day what she wanted, yesterday she wanted, she's been asking, a lot of people want intact hearts these days, they're looking for specific nodes. AV nodes, yesterday I was like wow, I didn't even know, good for them. Yesterday was the first time she said people wanted lungs. And then, like I said, always as many intact livers as possible. People just want—**
>
> Buyer: **Yeah, liver is huge right now.**
>
> [PP Witness #1]: **Some people want lower extremities too, which, that's simple. That's easy. I don't know what they're doing with it, I guess if they want muscle. . . .**
>
> Buyer: And so, if it's something as simple as converting to breech that doesn't require a separate consent? Does that make the procedure take longer? Is that another step for the provider?
>
> [PP Witness #1]: No, it's just what you grab versus what comes out. It doesn't make anything any different.[978]

3. Training of Clinic Personnel and Doctors is Required to Improve the Likelihood of Intact Tissue from an Abortion

The Panel also sought to investigate the impact on the conduct of all clinic employees under a contractual environment with an outside fetal tissue procurement company. For example, would such a contract lead to a change in training personnel about the importance of conducting the abortion procedure in such a way that promotes the harvesting of intact fetal organs?

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[977] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform FNNF0991_20140408125926 (emphasis added).

[978] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] at 12-13 (July 25, 2014) (emphasis added), Exhibit 8.30.

> PP: The other consideration I think you guys need to make, is who does the training. Because when they do the training, you're basically guaranteed to not get anything.
>
> Buyer: Oh, you mean when it's a provider who's been training.
>
> PP: One who's training, who's basically doing the procedure, it comes out in a thousand—you're not going to get anything intact, so. What we did for a while, and I think it worked pretty well **if there's a trainee, I'd say, any research case, I'll do.** And as you get better, I'll let you do more, but we really need to do this, intact.[979]

This section of transcript provides a further inference that some doctors "work at" their abortion technique in a way that promotes intact fetal organs, while others who are just starting or who are less experienced will produce an abortion that "comes out in a thousand parts."

Some Planned Parenthood doctors took a cavalier approach to providing fetal tissue to a middleman company. In another video,[980] one of the journalists is talking to two Planned Parenthood Gulf Coast workers, [PPGC Abortion Services Official] and [PPGC Abortion Doctor]. They are both excitedly talking about partnering with Biomax (the fake TPC company) and the thrill of pulling out intact body parts. [PPGC Abortion Services Official] leans over to the journalist and says, **"We're a little different than other providers . . . Yeah I'm like, 'Yeah I have like a leg for you!' I'm like, oh shit, if other people were to hear me they'd be like, 'You are f[redacted]ing evil.'"**

4. Panel Interviews Consistent with the CMP Undercover Videos

The Panel did not set out to prove or disprove the veracity of the CMP videos. Instead they were viewed as citizen "leads" that might reveal matters that impact the effectiveness of federal law. The Panel conducted transcribed interviews with Planned Parenthood executives, policy makers, and abortion doctors to further investigate the influence of a contracted tissue technician in Planned Parenthood affiliate clinics. The transcript below recounts a series of questions between Panel staff and a Planned Parenthood executive about the relationship between the doctor and the tissue technician:

> BY MR. BELL:
>
> Q Now, do you think that doctors in your position should huddle in the morning?
> You say, "I like to do that." It's sort of an ongoing tense.

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[979] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] at 13 (July 25, 2014) (emphasis added), Exhibit 8.30.

[980] Center for Medical Progress videotape produced to the Committee on Oversight and Government Reform, FNND0569_20150419155634.

Do you think the doctors should huddle with a tissue tech to see what they're procuring, is on their list that day?

A I don't really have a feeling as to whether other doctors did. I like to be helpful.

Q And so you found it helpful that at least on this one day to huddle with the tissue tech and learn what [Procurement Technician] was searching for, what orders she had; is that right?

A I would ask her what tissue she was looking for, yes.

Q All right. Do you think that's a good idea for the whole fetal tissue donation program, that doctors and the tissue techs huddle each morning to discuss what they're going to try and procure that day?

A I think it could be helpful.[981]

After establishing that [PP Witness #1] believed that it would be helpful to meet with the contract tissue technician, she was asked whether she believed the method of the abortion could be changed to increase the likelihood of success:

BY MR. BELL:

Q Let's skip down just a couple lines. You say, "You know, everyone ha[s] [sic] a different technique. So that's the thing. There's definitely local variance like, you know, no two people do a C section the same way; no two people do a hysterectomy the same way; no two people do a D&E the same way."

And this is the part I'm interested in getting your opinion on. "With that said, if you maintain enough of a dialogue with the person who's actually doing the procedure so they understand what the end game is, there are little things, changes they can make in their technique to increase your success."

What did you mean by that sentence?

A I mean exactly what it said, which is their—**providers can change their technique to increase success**.

Q What would that—what would be that change in technique?

A I can't speak for every provider. If—every procedure is different. Providers make changes in technique as they're doing a procedure

[981] Transcribed Interview of [PP Witness #1] at 142 (Oct. 6, 2016), Exhibit 8.31.

the whole time for a variety of reasons. There are probably a myriad of changes that can be made.

Q Okay. Which ones could be made to increase the success of a fetal tissue donation?

A That's a very broad question and I think unless we were talking about a specific procedure I couldn't answer it for you.

Q "There are little things they can make in their technique to increase your success." What are those little things?

A Again, as I mentioned, **a change in instruments, a change in where they're grasping the tissue. These are changes in technique that a provider can make for a variety of reasons.** I—

Q **But it could be made to increase the success of fetal tissue donation.**

A Yes, that's what I'm saying.

Q Okay. Now, so those little techniques that you just described, if there was no fetal tissue donation to increase the likelihood of success, they wouldn't—they wouldn't make those little changes, would they?

A Well, providers make changes in technique for a variety of reasons.

Q Right. They would making them for other reasons, other than likelihood of success; isn't that right?

A [Pause.]

Mr. Bopp. Why don't you ask her the question directly, if she ever changes technique in order to—

Mr. Bell. Well, you suggest that providers may include—there are little things they can make in their technique to increase their success. You said what those were.

BY MR. BELL:

Q Now, the question is: if there was no fetal tissue donation, those little things, changes that would be made to increase their likelihood of success, those wouldn't be made, would they?

A Well, I can't say across the board they wouldn't be made because there's probably other reasons that a provider during a procedure—

Q **They wouldn't be made for the purpose of getting fetal tissue, would they?**

A **No, they wouldn't.**

Q So they would be made for other reasons.

A Yes.

Q **So one set of little changes is chosen for other medical reasons, and one set of little changes could be chosen to increase the likelihood of success.**

A **Yes.**

Q Thank you.[982]

It is clear that the PPFA executive in charge of directing the MS&G guidelines, [PP Witness #1], altered the method of the abortion procedure in her own practice. It is also clear that she has not complied with the directive of the MS&G manual regarding the requirement to affirm that the method of the abortion has *NOT* been changed to promote fetal tissue donation. The guidelines specifically require, "Notation signed by the clinician performing the abortion that . . . . no substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the blood and/or tissue.[983]

During an interview with Panel staff, [PP Witness #1] was asked:

Q Do you sign those documents after every abortion you've participated in where there was a donation of blood or tissue?

A Are you asking me if I have personally signed a—a statement to this effect?

Q Yes.

A **I have never signed a statement to this effect.**

Q Have you ever been a clinician performing an abortion?

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[982] Transcribed Interview of [PP Witness #1] at 181-82 (Oct. 6, 2016) (emphasis added), Exhibit 8.32.
[983] Programs for Donation of Blood And/Or Aborted Pregnancy Tissue For Medical Research, Education, or Treatment (Revised, June 2011) [PPFA-HOU_E&C-000029-30], Exhibit 8.33.

A I think we know I have.

Q But this is in the manual, and it says that someone is supposed to sign this document noting these three square bullets. Am I misunderstanding something?

A No, I don't think you are. . . .

Q. Well, you never signed on at any PP where you worked.

A That's correct.[984]

G. Planned Parenthood Affiliates Violated the Federal Guidelines on Patient Consent

1. Summary

Planned Parenthood affiliates were provided a form as part of the MS&G guidelines to obtain consent from patients for fetal tissue donations.[985] Some affiliates contracted with tissue procurement businesses (TPB's) who embedded technicians inside the affiliate clinics and who also provided their own version of a patient consent form.[986] The Panel learned that the form sanctioned for use by PPFA and used by Planned Parenthood abortion clinics and the forms often provided by outside TPB's do not meet federal consent requirements. Under the principles outlined in the Belmont Report, human research subjects must provide informed consent before they participate in a study. During the Panel's hearing on *Bioethics and Fetal Tissue*, witnesses agreed that Planned Parenthood's consent form was insufficient for obtaining informed consent.[987] Further, a comparison of Planned Parenthood's form and the form used by another fetal tissue supplier highlights the stark differences between a consent process that fails to meet federal requirements and a sufficient consent process. Finally, Planned Parenthood executives admitted that the form was legally insufficient.

2. Legal background[988]

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created on July 12, 1974, with the enactment of the National Research

[984] Transcribed Interview of [PP Witness #1] at 178-82 (Oct. 6, 2016), Exhibit 8.32
[985] Planned Parenthood consent form, [STEM.HOUSE.OGR_000007-8 / STEM.HOUSE.SELECT_0173-4] Exhibit 8.34
[986] Stem Express consent form, [STEM.HOUSE.OGR_00009-12 / STEM.HOUSE.SELECT_0175-0178] See Exhibit 8.35
[987] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., (unedited transcript) (Mar. 2, 2016) (testimony of Paige Cunningham, at 77, testimony of Lawrence Goldstein at 149). http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf
[988] For a more detailed examination of these laws, see Chapter 2 *supra*.

Act.[989] The need for this Commission and for standardized protections for human research subjects became painfully evident after the Tuskegee Syphilis study received public scrutiny in 1972. One of the striking problems with the Tuskegee Syphilis study was the complete absence of informed consent from study participants. There was no evidence that the researchers had informed the participants, who thought they were receiving medical treatment, of the study or its real purpose—in fact, they were *misled* and "had not been given all the facts required to provide informed consent."[990]

Given that background, it is not surprising that "respect for persons" is one of the three principles of biomedical research included in the Commission's Belmont Report. Obtaining informed consent from patients or study participants is a critical component of respecting persons. Today, laws and regulations require informed consent from study participants. Under the "Common Rule,"[991] human subjects must give informed consent before research may take place. Further, an Institutional Review Board (IRB) must review the proposed research project, and IRB approval requires researchers to obtain informed consent.[992] Also, under federal law, research using fetal tissue requires a mother's written consent.[993] State anatomical gift acts also require informed consent.

3. The Panel asks experts to evaluate Planned Parenthood's consent form

During the Panel's hearing on *Bioethics and Fetal Tissue*, Rep. Vicky Hartzler (MO-4) addressed an important statement in the Belmont Report regarding informed consent—that "inducements [to consent] that would ordinarily be acceptable may become undue influences if the [research] subject is especially vulnerable."[994] She asked an ethics expert if a form known to be widely used by Planned Parenthood abortion clinics to obtain a mother's consent to donate fetal tissue complied with "HHS's mandate against inducement."[995] The form stated:

> Research using the blood from pregnant women and tissue that has been aborted has been used to treat *and find a cure* for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."[996]

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[989] P.L. 93-348.
[990] *See* The Tuskegee Timeline, CDC, http://www.cdc.gov/tuskegee/timeline.htm.
[991] 45 C.F.R. § 46.
[992] 45 C.F.R. § 116.
[993] 42 U.S.C. § 289g-1.
[994] The Belmont Report, Office of the Sec., Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.
[995] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong. At 77 (unedited transcript) (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.
[996] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., Majority exhibit A-3 (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD030.pdf (emphasis added).

The witness agreed that this was an important question, because the "idea of the promise of cures" found in the form was a "very powerful motivator."[997] The witness also indicated that the "consent" form was deficient in other ways: "The concern I have is that the standards that we have typically for fetal tissue donation are just absent here. And so in addition to the voluntariness, there is just the thoroughness of the consent [that] seems to be missing in this form."[998]

A researcher invited by the minority to testify agreed, stating that the form would not have "made it past" his IRB.[999] The testimony provided by all witnesses invited by both the majority and minority raised concerns that the principles embodied in the Belmont Report, and later incorporated into federal regulations, are not being followed by abortion providers seeking consent for the donation of human fetal tissue.

4. Planned Parenthood's consent form is inadequate compared to other entities' consent forms

The stark contrasts between Planned Parenthood's consent form and forms used by other entities providing fetal tissue further demonstrate the inadequacies of Planned Parenthood's "consent" process. In addition to containing wildly inaccurate claims about past results from fetal tissue research, Planned Parenthood's one-page form fails to provide basic information about the purpose for which the donation is being sought and the precise nature of the "pregnancy tissue" being donated.

The University of Washington Birth Defects Research Laboratory's lengthy consent form, in contrast, states the purpose of the study (*i.e.*, to study birth defects and other diseases), and graphically describes aspects of the fetal tissue procurement process. Further, the form acknowledges that "[e]xamples of tissue collected and sent to scientists for study are: brain, liver, kidney, ovary or testis, eyes, and skin."[1000] In other words, the mother is being asked to donate her deceased infant's body parts, not mere "pregnancy tissue" (as it is described in the Planned Parenthood form).

The Panel also uncovered a series of tissue procurement contracts between StemExpress and three abortion clinics: Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS). PPMM and PPSP may have used both StemExpress' consent form and the Planned Parenthood consent form described

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[997] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 77 (unedited transcript) (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.

[998] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 77 (unedited transcript) (Mar. 2, 2016) (testimony of Paige Cunningham), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.

[999] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 149 (unedited transcript) (Mar. 2, 2016) (testimony of Lawrence Goldstein), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Transcript-20160302.pdf.

[1000] University of Washington Birth Defects Research Laboratory, Consent form for the Donation of Embryonic or Fetal Tissue, Exhibit 8.36.

above. StemExpress' form also fails to meet federal requirements and leads with extravagant promises:

> Research using donated tissue and blood is *currently underway* to uncover the causes of and *ultimately find cures* for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and many more.[1001]

Further, the StemExpress form fails to provide any details regarding the purposes for which donated tissue may be used. Like Planned Parenthood's form, the StemExpress form refers to "pregnancy tissue" without acknowledging the nature of that tissue (*e.g.*, fetal heart, lungs, eyes).

5. The Planned Parenthood consent form does not indicate whether the tissue will be used for education, research, or treatment, including transplantation

As discussed above, the Planned Parenthood consent form does not provide any detailed information about how donated fetal tissue will be used—the form simply states that "blood and/or the tissue from the abortion [will be] used for education, research, or treatment." Further, the form states that the patient "understand[s] that there will be no changes to how or when [her] abortion is done in order to get [her] blood or the tissue."[1002]

Given that neither the abortion provider nor the patient knows the intended use for the tissue, and that the consent form explicitly states that there will be "no changes" to the patient's abortion procedure, Planned Parenthood is obligated to comply with the federal law stating, "No alternation of the timing, method, or procedures used to terminate the pregnancy [may be] made solely for the purpose of obtaining the tissue."[1003]

Planned Parenthood Executives agreed that the consent form was legally insufficient

During an interview with Panel staff, [PP Witness #1] agreed that Planned Parenthood's consent form was problematic:

> If I'm evaluating the form now, you are correct. To my knowledge there is no cure for AIDS. So that is probably an inaccurate statement. . . . a consent form should not have an incorrect statement.[1004]

[PP Witness #2] stated, "I would agree that that is insufficient for obtaining informed consent, correct."[1005]

[1001] *See* Exhibit 8.34
[1002] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., Majority exhibit A-3, at 3 (Mar. 2, 2016), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD030.pdf.
[1003] 42 U.S.C. § 289g-1(b)(2)(A)(ii).
[1004] Transcribed Interview of [PP Witness #1] at 131-32 (Oct. 6, 2016), Exhibit 8.37.
[1005] Transcribed Interview of [PP Witness #2] at 45 (Oct. 19, 2016), Exhibit 8.38.

6. PPFA Executive suggests that the middleman obtain the consent to donate tissue

Even with the admission that PPFA consent form is adequate, the following excerpt from an undercover video by investigative journalists reveals how [PP Witness #1] explained to a potential TPB how to provide a comprehensive service that would be attractive to surgical abortion centers. In particular, the advice focused on the embedded tissue technician doing the consent.

> [PP Witness #1]: I would say, barring [sic] some bizarre space issue, because some places have very limited space. Some people would be happy to do as little for you as possible. The more you can do for them, the easier it is. **That includes consenting the patients—**
>
> Buyer: Right, because I was imagining [we] would be doing consent a well.
>
> [PP Witness #1]: That's probably the biggest inconvenience, ugh that's one more thing my staff has to talk about. **They only have so many minutes to talk to the patient.** If you said you're going to do all the consenting, you're going to collect the tissue, I don't know who would really say no. I really don't.
>
> Buyer: That's really what they want to hear.
>
> [PP Witness #1]: That's what they want to hear, they want to hear you basically say, other than taking up a little bit of space, this is going to be as low impact as possible, on you and your flow. You're going to need a room, somewhere to consent the patients, once the patient is ready to be consented. So, you're going to need space in the lab, you're going to need a place to consent. That's it, otherwise, as long as you don't leave anything behind, they're going to be happy. There are affiliates who have been doing this for so long, they have staff that are so good at it, they may just say, that it's something that staff can do. Especially because you know, they know how to identify some stuff. They probably wouldn't know how to identify the stuff you need. They're looking for basically, all of the limbs a thorax a head, to present them, "We've got it all." That's the only concern.[1006]

The "buyer" then asks about the time that an abortion clinic staff spends with the patient. This time frame is particularly limiting to the integrity of the consent process.

[1006] Center for Medical Progress, Transcript of Meeting with [PP Witness #1] at 13-14 (July 25, 2014), Exhibit 8.39.

[PP Witness #1]: How long, right now, is the average amount of time they spend with a patient?

PP: I would say about ten minutes.

[PP Witness #1]: Per patient.

PP: Per patient. yes. And also contraceptive counseling and all that.

Buyer: That's all pre procedure, pre op.

[PP Witness #1]: The layout of the actual Planned Parenthood is counseling rooms and procedure rooms. So, yea those are just counseling rooms with a desk and a chair.

Buyer: Certainly, I'm not an expert in your clinic flow, I don't presume to know where would best fit in. But, I know that what we've done for other practices, for example the cosmetic facilities. We have a clinic float, our tech kind of acts as a float, they have their clipboard, and kind of mark down all the interested patients, you know ahead of time to try to facilitate that. I don't know if that will help or hinder your process.

[PP Witness #1]: That's how it works with a lot of the researchers, as well. They kind of just identify who is interested.[1007]

H. StemExpress and Planned Parenthood abortion clinics appear to have committed systematic violations of HIPAA

1. Summary

As discussed above, the Panel's investigation uncovered a series of business contracts between StemExpress[1008] and several Planned Parenthood abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the Planned Parenthood abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

StemExpress and at least two of these Planned Parenthood abortion clinics—Planned Parenthood Mar Monte (PPMM) and Planned Parenthood Shasta Pacific (PPSP)—appear to have committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule from about 2010 to 2015. These violations occurred when the Planned Parenthood clinics intentionally disclosed patients' individually identifiable health

[1007] *See id.*

[1008] StemExpress and Stem-Ex are the same company.

information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

The Panel filed a complaint against each of these entities requesting a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services on June 1, 2016.

2. Legal Background

As discussed above,[1009] the HIPAA privacy rule (Privacy Rule) protects all "protected health information" (PHI) held or transmitted by a covered entity or its business associate.[1010] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual, and includes demographic data relating to an individual's health condition, health care, or payments for the provision of health care.[1011] A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,[1012] or as the individual or their representative authorizes in writing. Civil monetary penalties may be imposed, and criminal fines or imprisonment can follow violations of the Privacy Rule.[1013]

3. Factual Background

The Planned Parenthood abortion clinics are "covered entities" under HIPAA while StemExpress is not.[1014] StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."[1015] From about 2010 to 2015, the Planned Parenthood abortion clinics collaborated with StemExpress by permitting StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain individually identifiable health information, or protected health information (PHI) about their patients; interact with patients; and seek and obtain patient consent for tissue donation.[1016] StemExpress embedded tissue procurement technicians inside the Planned Parenthood abortion clinics whose work sequence followed a daily routine:

1) A researcher/customer placed an order for human fetal tissue using an online business portal provided by StemExpress, requesting a particular gestational range for the fetal tissue.[1017]

[1009] *See* Chapter II.A.4 *supra.*
[1010] 45 C.F.R. § 160.103.
[1011] *Id.*
[1012] 45 C.F.R. § 164.502(a).
[1013] Pub. L. 104-191; 42 U.S.C. §§ 1320d-5–1320d-6.
[1014] *See* 45 C.F.R. Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) *See also* OCR Privacy Brief, Summary of the HIPAA Privacy Rule, http://www.hhs.gov/sites/default/files/privacysummary.pdf (used as reference throughout this section).
[1015] StemExpress, About Us, http://stemexpress.com/about/.
[1016] *See* Clinic Procedures & Policies, Exhibit 8.40.
[1017] *See* Researcher Procurement Record, Exhibit 8.41.

2) The Planned Parenthood abortion clinic faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.[1018]

3) The day the abortion procedures were scheduled, StemExpress posted the order on a website "task board" (order page) to be accessed by their procurement technician planted in the Planned Parenthood abortion clinic, or communicated the order to the tissue technician via email.[1019]

4) The StemExpress procurement technician informed the Planned Parenthood clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic staff member provided the medical files, including PHI, for the patients with abortions scheduled for that day.[1020]

5) The StemExpress procurement technician then sought out particular patients *by name* and obtained their consent to donate fetal tissue while they were awaiting their procedures. The Planned Parenthood abortion clinic also permitted the procurement technician to interview patients and *obtain their PHI.*[1021]

6) StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page.[1022]

7) StemExpress paid the Planned Parenthood abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for resale to the researcher.[1023]

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the Planned Parenthood abortion clinics did not have a reason to provide, patients' PHI. Instead, the Planned Parenthood abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefited StemExpress and the Planned Parenthood abortion clinics.[1024]

[1018] *See* Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress (Jan. 10, 2013), Exhibit 8.42.
[1019] *See* Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Navigating the Task Board, Exhibit 8.43.
[1020] *See* StemExpress Emails, Exhibit 8.44.
[1021] *See* Clinic Procedures and Policies, *See* Exhibit 8.40; Consenting Patients, Exhibit 8.45.
[1022] *See* Procurement Technician Compensation Policy for Tissue and Blood Procurement, Exhibit 8.46.
[1023] See StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439, Exhibit 8.47.
[1024] *See* Standard Operating Procedure, Exhibit 8.48.

4. The Contracts between StemExpress and the Planned Parenthood abortion clinics

Particular language, contained within the four corners of the written contracts between StemExpress and the Planned Parenthood abortion clinics, raises serious concerns that the parties violated the Privacy Rule:

> [a]ny information obtained from [the Planned Parenthood abortion clinics] patients' charts shall be privileged, and [Stem-Ex/StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex/StemExpress] will not receive any information concerning identity of donors *except as necessary* to obtain patients' consent for use of POCs and maternal bloods (emphasis added).[1025]

This admission, on the face of the contracts, that the Planned Parenthood abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI *prior to* obtaining patients' consent to donate fetal tissue *or* patients' authorization to view their PHI.

5. Violations of the HIPAA Privacy Rule by StemExpress and the Planned Parenthood Abortion Clinics

The agreements between StemExpress and the Planned Parenthood abortion clinics, on their face and in practice, appear to be fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" cannot trump a law *prohibiting* the Planned Parenthood abortion clinics from permitting these disclosures in the first place. As discussed below, the Planned Parenthood abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The Planned Parenthood abortion clinics and StemExpress violated the HIPAA privacy rule because: (1) The disclosures of patients' PHI made by the Planned Parenthood abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye, or tissue transplantation, or for research; (2) The consents for fetal tissue donation ostensibly obtained by StemExpress from the Planned Parenthood abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (3) The disclosures of patients' PHI made by the Planned Parenthood abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (4) StemExpress is not a *Business Associate* of the Planned Parenthood abortion clinics under HIPAA.

[1025] *See* Contracts, Exhibit 8.49 (emphasis added).

6. The disclosures of patients' PHI made by the Planned Parenthood abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye, or tissue transplantation, or for research

The disclosures of PHI that the Planned Parenthood abortion clinics made to StemExpress are neither required[1026] nor permitted[1027] by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.[1028] Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers, and the Planned Parenthood abortion clinics benefited from this arrangement because StemExpress paid them for the tissue.

a) Cadaveric organ, eye, or tissue transplantation

Importantly, Planned Parenthood's disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act,"[1029] the Planned Parenthood abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for *research,* which is not covered by the cadaveric organ, eye, or tissue exception.[1030]

b) Research

Further, Planned Parenthood's disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board (IRB) for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.[1031]

c) Violations Preceding "Consent"

Because StemExpress employees actually sought consent for tissue donation from patients, the Planned Parenthood abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past

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[1026] 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).
[1027] *See* 45 C.F.R. § 164.502(a)(1).
[1028] *See* 45 C.F.R. § 164.506(c).
[1029] 42 U.S.C. § 274e(c)(1).
[1030] *See* 45 C.F.R. § 164.512(h).
[1031] 45 C.F.R. § 164.512(i).

and present medical treatment, and more. Each time a Planned Parenthood employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.

No evidence suggests the Planned Parenthood abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The Planned Parenthood abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set[1032] regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the Planned Parenthood abortion clinics to StemExpress were inarguably direct and intentional—not incidental.[1033] StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her Planned Parenthood healthcare provider in blatant violation of the HIPAA privacy rule.

7. The consent for fetal tissue donation obtained by StemExpress from the Planned Parenthood abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule. The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.[1034] Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.[1035]

Neither the consent form provided by StemExpress nor the consent form provided by Planned Parenthood to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.[1036] The statement in the StemExpress form that a patient's "health information will be protected at all times" is ironic given that StemExpress' possession of the patient's PHI already placed the Planned Parenthood abortion clinics and StemExpress in violation of the HIPAA privacy rule.

[1032] *See* 45 C.F.R. § 164.514(e).
[1033] *See* 45 C.F.R. § 164.502(a)(1)(iii).
[1034] 45 C.F.R. § 164.508.
[1035] 45 C.F.R. § 164.508(c).
[1036] *See* StemExpress consent form, Exhibit 8.35, and Planned Parenthood consent form, Exhibit 8.34.

The StemExpress form also stated that "[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier."[1037]

Like the privacy provision in the contracts between StemExpress and the Planned Parenthood abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The StemExpress form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The StemExpress form did not state who will disclose or use the patient's PHI. It also did not state when the patient's authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The Planned Parenthood form, purportedly used to obtain patient consent for human fetal tissue donation at Planned Parenthood Mar Monte and Planned Parenthood Shasta Pacific,[1038] was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient's PHI to researchers or others; or the patient's right to revoke her authorization in writing.

One former StemExpress procurement technician, [Procurement Technician], was embedded at several California Planned Parenthood clinics and told investigative journalists of repeated consent violations she witnessed during her time with Planned Parenthood. In one instance, [Procurement Technician] told a StemExpress coworker that a woman had refused to consent to a blood draw for donation, but the coworker—with full knowledge of the patient's refusal—drew her blood anyway the following day without telling her it was for StemExpress.[1039]

8. The disclosures of patients' PHI made by the Planned Parenthood abortion clinics to StemExpress were not the minimum neeessary disclosures to facilitate the procurement of human fetal tissue from aborted infants

The Planned Parenthood abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the "minimum necessary" PHI to facilitate the procurement of human fetal tissue from aborted infants.[1040] StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients' consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by Planned Parenthood employees.

[1037] StemExpress Consent Form, Exhibit 8.35.
[1038] Planned Parenthood consent form, Exhibit 8.34.
[1039] Human Capitol-Episode 2: Inside the Planned Parenthood Supply Site (YouTube) https://www.youtube.com/watch?v=ABzFZM73o8M (5 minutes, 30 seconds).
[1040] 45 C.F.R. §§ 164.502(b) and 164.514(d).

As addressed above, the Planned Parenthood abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue for which Planned Parenthood would be paid, and that would later be sold by StemExpress to researchers at a huge mark-up.

9. StemExpress is not a *Business Associate* of the Planned Parenthood abortion clinics under HIPAA

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.[1041]

Clearly, StemExpress did not perform any of these services for the Planned Parenthood abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the Planned Parenthood abortion clinics' patients.

[1041] 45 C.F.R. § 160.103.

IX. Biomedical Research and Human Fetal Tissue

Chapter IX Redaction Key:

Chapter IX cites numerous academic articles. None of the individuals in this chapter were part of the Panel's investigation into transactions involving fetal tissue. Thus, the names are left unredacted due to their academic contribution to biomedical research.

A. Success of the United States Biomedical Research Enterprise

The United States of America is a global leader in scientific research. A comprehensive report of world-wide research investment indicates that the 2014 gross expenditure on Research and Development (R&D) in the United States exceeded $485 billion, or nearly 27% of the global R&D budget.[1042] The same pattern holds for U.S. investment in biomedical research. A recent report in the New England Journal of Medicine indicates that the 2012 biomedical research expenditures in the United States exceeded $119 billion, with the next largest national investment being made by Japan, at just over $37 billion.[1043] Corresponding to this strong financial commitment, the United States is also global leader in biomedical research publication and innovation. For example, between 2000-2013, the Unites States published approximately 40% of all papers in the area of stem cell research, with the next closest contributor (the United Kingdom) producing less than 10% of all published research in this rapidly advancing field.[1044]

The National Institutes of Health (NIH) invests approximately $32 billion annually in medical research, funding over 300,000 researchers both in the United States and around the world.[1045] The NIH research portfolio includes over 83 thousand active projects.[1046] In addition, there are currently over 228 thousand U.S.-funded clinical trials both within the U.S. and abroad.[1047] This represents a massive research effort directed both at understanding the basic mechanisms of human disease and at discovering novel treatments to relieve human suffering.

American citizens have every right to be proud of the research enterprise in our country, and are wise to support it with tax dollars. The House Select Investigative Panel shares this support. We are strongly committed to promoting both basic and clinical research. However, as the history of biomedical research in the 20th century clearly demonstrates, when scientific research is uncoupled from either ethics or the law, grave injustice can result.[1048] Protections for

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[1042] 2016 Global R&D Funding Forecast, https://www.iriweb.org/sites/default/files/2016GlobalR%26DFundingForecast_2.pdf.

[1043] Asia's ascent—global trends in biomedical R&D expenditures. Chakma J, Sun GH, Steinberg JD, Sammut SM, Jagsi R. N Engl J Med. 2014 Jan 2;370(1):3-6.

[1044] Human embryonic and induced pluripotent stem cell research trends: complementation and diversification of the field. Kobold S, Guhr A, Kurtz A, Löser P. Stem Cell Reports. 2015 May 12;4(5):914-25.

[1045] https://www.nih.gov/about-nih/what-we-do/budget.

[1046] 83,592 Active Research Projects. https://projectreporter.nih.gov.

[1047] 228,702 Clinical trials; https://www.clinicaltrials.gov.

[1048] For example, see: Some conditions of obedience and disobedience to authority. Milgram S. Int J Psychiatry. 1968 Oct;6(4):259-76; The Tuskegee study of untreated syphilis. Kampmeier RH. South Med J. 1972

the rights of patients and provisions for the ethical oversight of research procedures are not designed to "hinder" the advance of science, but rather to ensure that the scientific enterprise more perfectly fulfills its promise to society by advancing efficiently, while also being both just and ethical.

The goal of the House Select Investigative Panel is not to oppose science, but rather to determine how best to support science, so that this important work can advance as rapidly as possible without ethical compromise. To accomplish this goal, it is important that biomedical research be accurately understood and that obstacles to research are realistically addressed. Unfortunately, a number of false and misleading assertions have been made regarding the role of human fetal tissue in modern scientific research—inaccuracies that must be corrected before progress towards the goal of promoting sound and ethical research can be realized. Moreover, the results of this Panel's investigation suggest that in some cases, aggressive tissue procurement businesses have created an artificial market for human fetal tissue, even when it is not the most scientifically powerful or appropriate research model (*e.g.*, for the study of adult-onset diseases, such as macular degeneration). Facilitating cost-effective and convenient access to the most appropriate research models requires an accurate view of when human fetal tissue is necessary and/or advantageous for modern biomedical research.

Below we address common claims regarding the contribution of fetal tissue to modern biomedical research (Section B) and respond directly to the false and misleading statements made in "*Setting the Record Straight: The Unjustifiable Attack on Women's Health Care and Life-Saving Research*;" *i.e.*, the Minority report of the House Select Investigative Panel, dated December 5, 2016 (Section C). We then present an objective analysis of current, long-standing research programs that utilize human fetal tissue (Section D), concluding with recommendations for improving access to appropriate scientific models, including (when necessary) human fetal tissue (Section E).

B. Response to the misleading and false arguments made by scientific societies, medical societies, and universities

In February, the ranking member of the House Select Investigative Panel, the Honorable Jan Schakowsky, asked universities, scientific societies and medical societies for "assistance in providing the Panel with information that will further our understanding" of the following three topics (see letter in Exhibit 9.1):

1) Past benefits of fetal tissue research.

2) Potential future benefits that might be gained through continued fetal tissue research.

3) Unique aspects of fetal tissue in research, in comparison with adult cells, stem cells, or other cellular organisms that might be used for research purposes.

Oct;65(10):1247-51; Experiments at the Willowbrook State School. Krugman S. Lancet. 1971 May 8;1(7706):966-7.

To date, we have received responses from the following institutions (Exhibit 9.2):

American Academy of Pediatrics (AAP)
American Association for the Advancement of Science (AAAS)
American College of Obstetricians and Gynecologists (ACOG)
Association of American Medical Colleges (AAMC)
Baylor College of Medicine
Children's Hospital of Pennsylvania (CHOP)
Columbia University
Dartmouth University
Harvard University
John Hopkins University
Oregon Health Sciences University (OHSU)
Rockefeller University
University of California Los Angeles (UCLA)
University of California San Diego (UCSD)
University of Colorado (UCO)
University of Illinois at Chicago (UIC)
University of Minnesota (UMN)
University of Pennsylvania
University of Wisconsin-Madison (UWM)
Yale University

There are a number of reasons why the specific questions posed by the ranking member have limited value. First, while the past benefits of human fetal tissue research may be of historical interest, experiments conducted a half-century or more ago are no more relevant to the practice of modern science than vacuum tube-technology is relevant to modern television manufacturing. Second, speculation on the "potential" future benefits of human fetal tissue research is simply that: speculation. Scientific societies and research universities are no more capable of predicting the future than anyone else. Finally, while the question of whether human fetal tissue provides unique benefits to research is important, not a single one of the responding institutions provided substantive evidence relevant to this question. The issues and arguments raised in the letters to the Panel fell into eight major areas that are addressed in detail below.

1. Concerns regarding the privacy and safety of researchers involved in human fetal tissue research

A number of letters (AAAS, Hopkins, UCLA, UCO, UMN) expressed concern that the investigation of the House Select Investigative Panel would reveal the identities of researchers, compromising their privacy and potentially putting them at risk for reprisal. Yet this concern appears to reflect a false belief that publicly funded scientific research is somehow exempt from the Freedom of Information Act.[1049] Moreover, in compliance with the National Institutes of

[1049] Freedom of Information Act, 5 U.S.C. § 552 *et seq. See generally* https://www.foia.gov/.

Health (NIH) Reform Act of 2006,[1050] detailed information on all grants that employ human fetal tissue is posted on a publicly available website,[1051] including the names of the researchers and links to their publications. Therefore, the scientists involved in human fetal tissue research, as well as the names and affiliations of their colleagues and collaborators, have already been identified by the NIH.

2. The false claim that human fetal tissue was used in the last century to produce vaccines for polio and other diseases

Several letters (AAAS, AAP, ACOG, Columbia, Harvard, OHSU, UCLA, UIC, UWM) claim that research on fetal tissue was required for production of the polio vaccine. A similar claim is made by a *Guttmacher Policy Review* article that states, "Fetal Tissue Research dates back to the 1930s, and has led to major advances in human health, including the virtual elimination of such childhood scourges as polio, measles and rubella in the United States."[1052] However, the facts simply do not support these claims.

a) Early vaccine research did not rely in any way on human fetal tissue

Vaccine research was begun by Edward Jenner in the late 1700s, *more than 100 years before the first published use of human fetal tissue for biomedical research in the 1920s.*[1053] Jenner developed a vaccine against smallpox in 1798 which ultimately led to the eradication of this devastating disease. In fact, vaccines against 8 diseases (Rabies, Diphtheria, Typhoid, Cholera, Plague, Tetanus, Pertussis and Bacille-Calmette-Guerin disease) were all developed in the 1800s and early 1900s, well before the first use of fetal tissue in research.[1054]

b) The polio vaccine was not produced using human fetal tissue

Work on the polio virus began in the 1930s, when our knowledge of how to culture human cells in the laboratory was quite primitive. Polio virus was first successfully propagated in the laboratory by Albert Sabin in 1936 using human fetal tissue cultures.[1055] This early result was important for advancing our understanding of polio, but did not directly result in a vaccine. Moreover, human fetal tissue has never been used to make the polio vaccine. Jonas Salk and

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[1050] National Institutes of Health (NIH) Reform Act of 2006, Pub. L. No. 109-482, 120 Stat. 3675 (2007).
[1051] https://projectreporter.nih.gov.
[1052] Fetal Tissue Research: A Weapon and a Casualty in the War Against Abortion. Boonstra, HD. Guttmacher Policy Review 2016 | Vol. 19, http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD011.pdf.
[1053] Addison's Disease, with Severe Anaemia, treated by Suprarenal Grafting. Hurst AF, Tanner WE, Osman AA. Proc R Soc Med. 1922;15(Clin Sect):19-20.
[1054] History of vaccine development. Stanley A. Plotkin, New York : Springer, c2010. *See also* Immunization Action Coalition Vaccine Timeline, http://www.immunize.org/timeline/.
[1055] Sabin A B, Olitsky P K. Cultivation of poliomyelitis virus in vitro in human embryonic nervous tissue. Proc Soc Exp Biol Med. 1936;34:357–359.

Albert Sabin used monkey cells to produce the Polio vaccine,[1056] and we are still using monkey cells to produce this vaccine today.

c) The Nobel Prize was not awarded for curing polio using fetal tissue

The Nobel Prize was awarded to John Enders, Thomas Weller, and Frederick Robbins in 1954 for work on the polio virus that involved human fetal tissue. However, the work of Enders, Weller and Robbins was not for "curing polio," but rather for basic research on the polio virus. Importantly, this work did not critically depend on the use of human fetal tissue; *i.e.*, we could have learned everything they discovered about polio using animal cells. Prior to the work of Enders, Weller and Robbins, people believed polio virus infected human brain tissue, because 1) this is the tissue most strongly affected in the disease and 2) the only successful propagation of polio virus in the laboratory used human fetal brain tissue. In their Nobel Prize awarded work, Enders, Weller and Robbins showed that in fact, polio virus could be harvested from cultures of multiple human tissues, both fetal[1057] and non-fetal.[1058]

Importantly, the central discovery for which the Nobel Prize was awarded had *nothing to do with the properties of human fetal cells*. Rather, the critical finding was that *polio virus could be propagated in a wide range of tissues.* This finding paved the way for Salk and Sabin to culture polio in monkey kidney cells to produce the polio vaccine. However, if Enders, Weller and Robbins had tried monkey cells or human foreskin fibroblasts before they tried human fetal tissue, they would have made the same discovery (that polio could be propagated in multiple cell types), and they still would have won the Nobel Prize for this discovery, *without* the use of human fetal cells.

d) The vaccine for Measles was not produced using human fetal tissue

Guttmacher asserts that fetal tissue research resulted in the eradication of measles, yet in reality, *fetal tissue and fetal cell lines were not used for development of the measles vaccine*. This vaccine was developed in 1963 by Peebles and Enders, using chicken eggs, human amnion cells (obtained from term placentas), and human kidney cultures obtained from adult surgical samples.[1059] The vaccine was tested on monkeys.[1060]

[1056] For a review of the treatment of polio, see Vaccine-derived polioviruses and the endgame strategy for global polio eradication. Kew OM, Sutter RW, de Gourville EM, Dowdle WR, Pallansch MA. Annu Rev Mierobiol. 2005;59:587-635.

[1057] Cultivation of the Lansing Strain of Poliomyelitis Virus in Cultures of Various Human Embryonic Tissues. Enders JF, Weller TH, Robbins FC. Science. 1949 Jan 28;109(2822):85-7.

[1058] Cultivation of poliomyelitis virus in cultures of human foreskin and embryonic tissues. Weller TH, Robbins, FC, Enders JF. Proc Soc Exp Biol Med. 1949 Oct;72(1):153-5.

[1059] Milovanovic MB, Enders JF, Mitus A. Cultivation of measles virus in human amnion cells and in developing chick embryo. Proc Soc Exp Biol Med. 1957;95(1):120–127.

[1060] Enders JF, Katz SL, Milovanovic MV, Holloway A. Studies on an attenuated measles-virus vaccine. I. Development and preparation of the vaccine: technics for assay of effects of vaccination. N Engl J Med. 1960;263:153–159.

e) The vaccine for Mumps was not produced using human fetal tissue

The Mumps virus vaccine (MumpsVax) was licensed by Merck in 1967, at roughly the same time as the vaccine for Measles—a period when it is claimed that human fetal tissue was "necessary" for vaccine research and development. However, like polio and measles, production of the Mumps vaccine did not rely on human fetal tissue. The Mumps vaccine was developed by Maurice Hilleman, who isolated a wild type virus from his daughter, Jeryl Lynn, who was recovering from mumps. Hilleman propagated the Mumps "Jeryl Lynn strain" of virus in three different animal culture systems: monkey cells, chick embryo fibroblast cells, and embryonated chicken eggs. The Mumps vaccine is still produced using embryonated chicken eggs today (Exhibit 9.3).

f) The vaccine for Rubella; an isolated case

Of the diseases commonly used to illustrate the purported use of fetal tissue for the development of vaccines, Rubella is the single case for which this claim is at least partially correct. However, fetal tissue was not used to produce the first vaccine for Rubella, and the subsequent use of fetal tissue to manufacture Rubella vaccine was largely due to historical, not scientific factors.

Attenuated Rubella virus was first isolated in 1966.[1061] The earliest Rubella strains used for research were obtained by rinsing the throats of infected individuals and propagating the virus in animal cell culture. Work with these strains led to the development of the first Rubella vaccines in 1969.[1062]

Given that human fetal tissue was not used to produce the first Rubella vaccine, what is the basis for the claim that fetal tissue was "necessary" for combatting this disease? Beginning in the 1930s and continuing as late as the 1970s, fetal tissue was often used for propagation of virus, simply because (at the time) there was limited understanding of how to work with human cells and fetal tissue is easier to grow in the laboratory. Beginning in the 1960s, several laboratories were able to chemically alter cells derived from aborted fetuses such that the cells would continue to divide indefinitely in culture. Two of these "transformed cell lines," WI-38[1063] and MRC-5[1064] (each derived from a single aborted fetus), proved to be very robust and were rapidly adopted by many investigators. In addition, one strain of the Rubella virus (RA 27/3) was

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[1061] Attenuated rubella virus. I. Development and laboratory characterization. Parkman PD, Meyer HM Jr, Kirschstein RL, Hopps HE. N Engl J Med. 1966 Sep 15;275(11):569-74.

[1062] Three rubella virus strains were licensed in the U.S. in 1969.: HPV-77 strain grown in dog-kidney culture (Rubelogen by Parke-Davis); HPV-77 grown in duck-embryo culture (Meruvax by Merck); and Cendehill strain grown in rabbit-kidney culture (Cendevax by RIT-SKF, and Lirubel and Lirutrin by Dow). See: http://www.immunize.org/timeline/

[1063] The serial cultivation of human diploid cell strains. Hayflick, L, Moorhead, PS. Exp Cell Res. 1961 Dec;25:585-621.

[1064] Characteristics of a human diploid cell designated MRC-5. Jacobs JP, Jones CM, Baille JP. Nature. 1970 Jul 11;227(5254):168-70.

isolated from an aborted human fetus in 1969,[1065] several years after the first isolation of attenuated Rubella from non-fetal sources and production of the first Rubella vaccine. The RA 27/3 Rubella strain was propagated in fetal-derived cell lines to produce an alternative Rubella vaccine.

For reasons that are unrelated to the fetal origin of the virus, the RA 27/3 strain proved to be very effective in eliciting a strong immune response, and earlier forms of the Rubella vaccine were abandoned. Consequently, the RA 27/3 strain (propagated in fetal-derived cell lines) is still used for production of Rubella vaccine today.[1066] But importantly, the Rubella vaccine developed using fetal tissue was not the *first* or the *only* Rubella vaccine produced. In contrast to the claims noted above, *human fetal tissue was not "required" for isolation and propagation of Rubella or for development of vaccines against this disease, even in the 1960s.*

3. False claims that the production of modern vaccines depends on human fetal tissue

Several letters (AAMC, AAP, ACOG, CHOP, Columbia, Dartmouth, Harvard, OHSU, Rockefeller, UCLA, UIC, UMN, UWM, Yale) suggest that human fetal tissue is used for modern vaccine production. In reality, none of the nearly 75 vaccine formulations currently licensed in the United States is produced using human fetal tissue (see Exhibit 9.3).

a) Historic use of fetal cell lines in vaccine production by pharmaceutical companies

The fetal-derived cell lines WI-38 and MRC-5 were adopted by the pharmaceutical industry as tools for the production of vaccines shortly after they were developed in the 1960s. And for a small minority of vaccines, these tools are still used today. However, these historic fetal-derived cell lines are still in use today for primarily economic, not scientific reasons.

Obtaining FDA approval for a new vaccine is very labor intensive and costly. Consequently, once FDA approval has been secured for a particular method of producing a vaccine, Pharmaceutical companies tend to rely on this method, to avoid incurring new costs associated with "validating" the safety and efficacy of new procedures. Three major Pharmaceutical players (Merck, GlaxoSmithKline and Sanofi) adopted the fetal cell lines MRC-5 and WI-38 in the 1970s, shortly after they were developed. These companies were successful in gaining FDA approval for vaccines produced in these cell lines, and have continued using them ever since. However, viable alternatives exist and are used by other pharmaceutical companies for production of very similar vaccines (see Exhibit 9.3).

[1065] Attenuation of RA 27-3 rubella virus in WI-38 human diploid cells. Plotkin SA, Farquhar JD, Katz M, Buser F. Am J Dis Child. 1969 Aug;118(2):178-85.
[1066] See: Plotkin SA. The History of Rubella and Rubella Vaccination Leading to Elimination. Clin Infect Dis. 2006 43 (Supplement 3): S164-S168.

b) Modern vaccine production and research

Of the nearly 75 vaccine formulations currently approved by the Food and Drug Administration for use in the United States,[1067] only 11 (directed against Zoster, Varicella, Rabies, Rubella, Hepatitis A, Polio and Adenovirus) are produced using historic, fetal-derived cell lines, and none are produced using freshly isolated fetal tissue. *Importantly, alternative vaccine formulations that do not rely on fetal-derived cell lines are available or all but five of these diseases* (Adenovirus, Hepatitis A, Rubella, Varicella and Zoster), and there is no scientific reason these vaccines could not be produced using animal cell lines. For example, although vaccines against Hepatitis A are produced using the historic fetal-derived cell line MRC-5, modern vaccines against the related Hepatitis B virus are produced using genetically engineered yeast cells. In fact, the vast majority of modern vaccines are manufactured using bacteria, yeast or animal cells—and all of them could be manufactured in this manner. Human fetal tissue is outdated technology that is not necessary for modern vaccine production or research. For example, current vaccine research for HIV/AIDS, Cancer, Malaria and Ebola does not rely on human fetal tissue (see Exhibit 9.3.).

4. Assertions that fetal tissue is necessary for the study of diseases that affect human brain development, including Zika and Down syndrome

Several institutions (AAAS, ACOG, CHOP, Columbia, Harvard, Hopkins, Rockefeller, UCLA, UIC, UMN, Penn and Yale) claim that human fetal tissue is required for study of human development, particularly brain development and human brain diseases, such as Zika and Down syndrome. Yet given the strong similarities between neural development in humans and in other mammalian species, this assertion is largely unwarranted. For example, less than 1% of the more than twenty thousand research articles returned by querying the NIH-maintained PubMed database[1068] for the term "neurogenesis" involve human fetal tissue. Moreover, the history of vaccine development for Cytomegalovirus (CMV), one of the most compelling parallels to the Zika virus, provides a clear illustration of why human fetal tissue is not required for the study of viruses that affect brain development.

The Zika virus has received a lot of attention, with many characterizing it as a "health crisis" and calling for immediate action—including expanded fetal tissue research to develop a vaccine and reduced restrictions on abortion to eliminate infected infants prior to birth.

And Zika is indeed an alarming virus. The Centers for Disease Control (CDC) estimates that if a woman is infected with Zika in the first trimester of pregnancy, there is a 1-13% risk that her child will be born with a serious brain defect, including microcephaly.[1069] Moreover, a recent

[1067] FDA approved vaccine formulations:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.
[1068] https://www.ncbi.nlm.nih.gov/pubmed.
[1069] http://www.nejm.org/doi/pdf/10.1056/NEJMp1605367.

study from Brazil,[1070] and a report by the CDC[1071] both suggest that Zika increases the risk of miscarriage, even for healthy infants who are not affected by the virus.

Understandably, Zika has become the focus of an intense research effort, with nearly 120 clinical and research articles published on the virus, most within the last few years.[1072] Importantly, only two of these have involved the use of fetal tissue.[1073] The major advances in our understanding of the Zika virus, published in world-renowned scientific journals such as *Lancet, The New England Journal of Medicine, Science*, and *Nature*, have not relied on the use of human fetal tissue at all.

Zika has only recently become the subject of intense scientific investigation, and therefore the potential role of human fetal tissue in this research is hard to predict. Yet Zika isn't the only virus that causes brain defects and miscarriage. Comparing Zika to similar viruses that have been investigated for a longer time provides a better measure of whether human fetal tissue is likely to be important in combatting this type of disease. And the best studied virus that affects brain development in a manner quite similar to Zika is Cytomegalovirus, or CMV.

Similar to Zika, if a mother becomes infected with CMV during the first trimester of her pregnancy, there is a 9% risk that her child will be born with a serious brain defect, including microcephaly (Fig. 1).[1074] Also similar to Zika, the effects of CMV on adults are mild, making it difficult for a pregnant woman to know for sure that she has been infected. Yet unlike Zika, CMV is a very prevalent virus, with an estimated 30-50% of women of childbearing age world-wide being infected.[1075] Consequently, the toll of CMV on women and their children is far greater than for Zika. The CDC estimates that 1 in every 750 children born in the United States,

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[1070] http://www.nejm.org/doi/pdf/10.1056/NEJMoa1602412.

[1071] http://www.cdc.gov/mmwr/volumes/65/wr/mm6508e1.htm.

[1072] Based on a search of the NIH PubMed database (http://www.ncbi.nlm.nih.gov/pubmed) using the following terms: ("zika virus" AND (("case reports"[Publication Type] OR "clinical study"[Publication Type] OR "clinical trial"[Publication Type] OR "clinical trial, phase i"[Publication Type] OR "clinical trial, phase ii"[Publication Type] OR "clinical trial, phase iii"[Publication Type] OR "clinical trial, phase iv"[Publication Type] OR "comparative study"[Publication Type] OR "controlled clinical trial"[Publication Type] OR "meta analysis"[Publication Type] OR "research support, american recovery and reinvestment act"[Publication Type] OR "research support, n i h, extramural"[Publication Type] OR "research support, n i h, intramural"[Publication Type] OR "research support, non u s gov't"[Publication Type] OR "research support, u s gov't, non p h s"[Publication Type] OR "research support, u s gov't, p h s"[Publication Type] OR "research support, u s government"[Publication Type])) NOT review[Publication Type].

[1073] Zika Virus Infection with Prolonged Maternal Viremia and Fetal Brain Abnormalities. Driggers RW, Ho CY, Korhonen EM, Kuivanen S, Jääskeläinen AJ, Smura T, Rosenberg A, Hill DA, DeBiasi RL, Vezina G, Timofeev J, Rodriguez FJ, Levanov L, Razak J, Iyengar P, Hennenfent A, Kennedy R, Lanciotti R, du Plessis A, Vapalahti O. N Engl J Med. 2016 Jun 2;374(22):2142-51. doi: 10.1056/NEJMoa1601824; The Brazilian Zika virus strain causes birth defects in experimental models. Cugola FR, Fernandes IR, Russo FB, Freitas BC, Dias JL, Guimarães KP, Benazzato C, Almeida N, Pignatari GC, Romero S, Polonio CM, Cunha I, Freitas CL, Brandão WN, Rossato C, Andrade DG, Faria Dde P, Garcez AT, Buchpigel CA, Braconi CT, Mendes E, Sall AA, Zanotto PM, Peron JP, Muotri AR, Beltrão-Braga PC. Nature. 2016 May 11;534(7606):267-71. doi: 10.1038/nature18296.

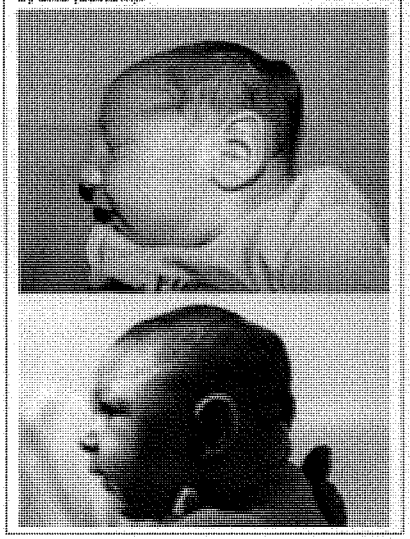
[1074] http://www.ncbi.nlm.nih.gov/pubmed/23297260; http://www.ncbi.nlm.nih.gov/pubmed/19800841.

[1075] CDC, Cytomegalovirus (CMV) and Congenital CMV Infection, http://www.cdc.gov/cmv/trends-stats.html#affected.

or over 5000 children each year, suffer permanent problems caused by CMV infection.[1076] CMV is clearly a health crisis for women and for children that is just as serious, if not more serious, than Zika.

So what are we doing about the CMV "crisis?" Shockingly, very little. We have known about CMV for over 100 years; the virus was originally isolated in the 1950s,[1077] but researchers have been aware of its effects on unborn children from as early as 1881.[1078] Since the 1950s, we have developed vaccines against measles, mumps, and a host of other viral diseases. Yet, despite many attempts, an effective vaccine against CMV has not been produced. And in the 60 years since the CMV virus was isolated, hundreds of thousands of American children with severe brain defects have been born, lived, and died, largely ignored by the media and by politicians.

Figure 1: Microcephaly caused by CMV (top) and by Zika (bottom).



CMV is truly one of the darkest stories in modern medicine. But thankfully, the story has recently been brightened by a glimmer of hope. Several candidate vaccines have been developed and are currently being tested in clinical trials, with promising results.[1079] After decades of disappointment, we may be close to preventing this devastating disease.

After so many years of fruitless effort, what has turned the tide on CMV? Perhaps surprisingly in the face of repeated claims that human fetal tissue is "necessary" to develop a cure for viruses that disrupt brain development, *fetal tissue has made almost NO contribution to modern CMV vaccine research* (Figure 2). Between 2010 and 2014 the NIH awarded over 75 grants focused on finding a vaccine to prevent CMV, and only one involved human fetal tissue.[1080] Similarly, there are 53 ongoing clinical trials of CMV-vaccines, and *not a single one* involves the use of human fetal tissue.[1081] The break-through on this devastating disease did not depend on human fetal tissue research at all.

[1076] *Id.*

[1077] http://www.ncbi.nlm.nih.gov/pubmed/9042169.

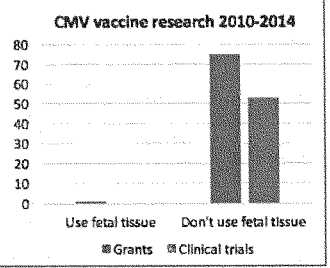
[1078] *Id.*

[1079] http://www.ncbi.nlm.nih.gov/pubmed/25791890.

[1080] Based on a search of the NIH grant database (https://projectreporter.nih.gov) over the years 2010-2014 for the terms "congenital cytomegalovirus", "vaccine related" and "human fetal tissue."

[1081] Based on a search of the NIH clinical trials database (https://www.clinicaltrials.gov) for the terms "CMV vaccine" and "fetal tissue."

Figure 2: Modern CMV research.



The breakthrough on a CMV vaccine came from basic scientific research using animal models, human cell lines, and adult human tissue. Scientists working with adult blood cells in the 1990s discovered a protein complex that was important for CMV infection.[1082] It was later discovered that in women with natural immunity to CMV, this same complex was the target of antibodies that effectively neutralized the virus.[1083] These findings led to successful vaccination experiments in animals[1084] that have rapidly lead to similar human clinical trials.[1085]

So what can we learn from CMV, a virus that is parallel in many ways to Zika? First, as frightening as Zika is, it is not a health care crisis, unless we are willing to admit we have been living with a largely ignored CMV "crisis" for the last 60 years. It is certainly true that both Zika and CMV take a heavy toll on children and families. They should both be fought aggressively with the best possible science and medicine. But hysterical calls for enhanced fetal tissue research and expanded abortion license are a matter of *POLITICS*, not medicine or science.

Second, developing an effective vaccine is sometimes a very difficult task. We know more about virology now than we did in the 1950s, but until very recently, CMV has resisted even our best modern efforts. We need to take a sober view of science and medicine, and accept that an effective, preventative vaccine for both CMV and Zika may be difficult to achieve—not because of any restrictions that may be placed on fetal tissue research, but because not every disease is easy to prevent.

Finally, we need to develop a more sophisticated view of how science and medicine actually work. The promising candidates for a CMV vaccine did not depend on fetal tissue research. They depended on observations of the natural human immune response and analysis of the CMV virus in cell lines and animals. We don't need human fetal tissue to develop a vaccine for Zika, and based on our modern experience with CMV, human fetal tissue is unlikely to provide a significant advantage in this fight (See Figure 2). The ethical research tools we have in hand are the best weapons against Zika, even if it proves to be as tenacious and confounding as CMV.

5. Assertions that human fetal tissue is vital for a wide range of life-saving research

Several letters (AAAS, CHOP, Dartmouth, Hopkins, OHSU, Rockefeller, UCLA, UCSD, UIC, UMN, Penn, UWM, Yale) voiced the opinion that human fetal tissue is "essential" (or "critical" or "vital") for a wide range of scientific investigations, often expressing alarm that

[1082] http://www.ncbi.nlm.nih.gov/pubmed/8397282.
[1083] http://www.ncbi.nlm.nih.gov/pubmed/19889756.
[1084] http://www.ncbi.nlm.nih.gov/pubmed/24297878; www.ncbi.nlm.nih.gov/pubmed/23107592.
[1085] *E.g.*, NCT00722839; NCT00439803.

cures would be delayed or prevented if human fetal tissue were not available for research. The same concerns were raised by Dr. Lawrence Goldstein in his March 2, 2016, testimony before the House Select Investigative Panel.[1086] Goldstein indicated that human fetal astrocytes are "vital" for his research on Alzheimer's disease and cannot be replaced by astrocytes derived from non-fetal or animal sources.

Yet all of these interlocutors fail to note that human fetal tissue research represents only a tiny fraction of the overall scientific enterprise. For example, of the 76,081 research grants funded by the NIH in 2014, only 160 (or approximately 0.2%) involved human fetal tissue.[1087] In the case of Alzheimer's disease specifically (the area of research singled out by Dr. Goldstein), a total of 1304 grants investigating Alzheimer's disease were awarded in 2014, *and not a single one involved fetal tissue*.[1088] Clearly, *the overwhelming majority of active, funded, research scientists—and the much larger number of their scientific peers who reviewed and endorsed these proposals for funding—have concluded that human fetal tissue is not "vital" for modern research on either Alzheimer's disease or other scientific questions.*

This fact raises a serious conundrum for those who claim human fetal tissue research is "essential" for advancing modern research. Given that the purpose of scientific peer review is to identify research proposals that use the most appropriate and powerful methods to address the most important scientific questions, why have the great majority of scientists elected not to employ human fetal tissue in their own research, and why have their scientific peers overwhelmingly endorsed this decision? Dr. Goldstein simply ignores this inconvenient reality, and presents his own minority opinion as if it reflected the view of the scientific community as a whole.

Dr. Goldstein also raises a second example of how human fetal tissue is "vital" for research, indicating that he uses such tissue in his attempt "to build new kidneys from stem cells," categorically asserting "it is only by examining this fetal tissue that it will be possible to determine the earliest biochemical signals that cells use . . . to make kidneys" (emphasis added). Yet Goldstein fails to note that substantial progress towards the goal of generating replacement kidneys *has already been accomplished* in other laboratories using stem cells from non-fetal sources.[1089] While Dr. Goldstein has clearly placed his faith in human fetal tissue research, his competitors have moved much more swiftly towards the goal of generating replacement organs

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[1086] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 149 (unedited transcript) (Mar. 2, 2016) (Testimony of Lawrence Goldstein), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Wstate-GoldsteinL-20160302.pdf.

[1087] https://projectreporter.nih.gov.

[1088] A search of the NIH database of funded research (https://projectreporter.nih.gov) for 2014 using the NIH spending categories "Alzheimer's Disease" and "Human Fetal Tissue" returned two projects: one "core facility" (P50 award) that does not specifically generate research on Alzheimer's and one award that mentions Alzheimer's Disease, but is in fact focused on Down syndrome.

[1089] Generation of kidney organoids from human pluripotent stem cells. Takasato M, Er PX, Chiu HS, Little MH. Nat Protoc. 2016 Sep;11(9):1681-92.; Kidney organoids from human iPS cells contain multiple lineages and model human nephrogenesis. Takasato M, Er PX, Chiu HS, Maier B, Baillie GJ, Ferguson C, Parton RG, Wolvetang EJ, Roost MS, Lopes SM, Little MH. Nature. 2016 Apr 27;536(7615):238.

using an ethically uncontroversial approach. And for patients, actual results are undoubtedly far more compelling than Dr. Goldstein's personal ideology.

Finally, consistent with the view that fetal tissue is "essential" for research, tissue procurement companies such as StemExpress market cells derived from fetal tissue as valuable scientific reagents, often charging thousands of dollars for a single preparation.[1090] Yet *all* of the cell types obtained from human fetal liver by StemExpress can be obtained from alternative sources (placenta, umbilical cord and umbilical cord blood); including CD34+ cells,[1091] CD36+ cells,[1092] CD133+ cells,[1093] and stromal (mesenchymal) stem cells.[1094] While some individual scientists (such as Dr. Goldstein) may believe that fetal cells are somehow "superior" to cells with the same characteristics that have been isolated from other sources, fetal cells clearly do not have "unique" properties. The role of tissue procurement companies in creating a market for cells derived from human fetal tissue is difficult to determine, but it is obvious that a wide range of stem and progenitor cells can be obtained from ethically uncontroversial tissue sources—and from sources that are often more relevant to the study of adult or neonatal disease than cells derived from fetal tissue.

6. Claims that human fetal tissue is required for clinical trials and cures

Several institutions (AAAS, Hopkins, Rockefeller, UCLA, UCSD, UIC, Yale) make this claim. In support of this view, Dr. Goldstein correctly notes in his March 2 testimony before the House Select Investigative Panel[1095] that neural stem cells derived from fetuses are currently being tested in clinical trials. He further suggests that medical treatments will be halted or delayed if fetal tissue is not available for research. A similar claim was made by the *Guttmacher Policy Review*, which states, "Clinical trials transplanting fetal cells are currently underway for people with spinal cord injury, stroke and ALS (Lou Gehrig's disease), and may soon begin for those with Alzheimer's disease, Parkinson's disease and multiple sclerosis."[1096]

[1090] StemExpress website on fetal liver, http://stemexpress.com/product-category/fetal-liver/.
[1091] A novel method of CD34+ cell separation from umbilical cord blood. Mehrishi JN, Bakács T. Transfusion. 2013 Nov;53(11):2675-80.
[1092] Extensive ex vivo expansion of functional human erythroid precursors established from umbilical cord blood cells by defined factors. Huang X, Shah S, Wang J, Ye Z, Dowey SN, Tsang KM, Mendelsohn LG, Kato GJ, Kickler TS, Cheng L. Mol Ther. 2014 Feb;22(2):451-63.
[1093] Isolation and characterization of CD133+CD34+VEGFR-2+CD45- fetal endothelial cells from human term placenta. Sölder E, Böckle BC, Nguyen VA, Fürhapter C, Obexer P, Erdel M, Stössel H, Romani N, Sepp NT. Microvasc Res. 2012 Jul;84(1):65-73.
[1094] Novel isolation strategy to deliver pure fetal-origin and maternal-origin mesenchymal stem cell (MSC) populations from human term placenta. Patel J, Shafiee A, Wang W, Fisk NM, Khosrotehrani K. Placenta. 2014 Nov;35(11):969-71.
[1095] *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. on Energy and Commerce*, 114th Cong., at 149 (unedited transcript) (Mar. 2, 2016) (Testimony of Lawrence Goldstein, at 110), http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Wstate-GoldsteinL-20160302.pdf
[1096] Fetal Tissue Research: A Weapon and a Casualty in the War Against Abortion. Boonstra, HD. Guttmacher Policy Review 2016 | Vol. 19, http://docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-20160302-SD011.pdf.

a) Fetal tissue is used in only a tiny fraction of clinical trials

Goldstein, Guttmacher, and the institutions noted above all fail to mention that human fetal tissue contributes to only a tiny fraction of the over 230 *thousand* clinical trials currently underway in the United States and around the world.[1097] A detailed examination of the studies indexed in the NIH database for clinical trials determined that there are currently only 7 studies involving transplantation of fetal tissue into patients (See Exhibit 9.4). Similarly, there are only 35 trials involving "stem cell lines" originally derived from human embryonic or fetal tissue (See Exhibit 9.4). Of these, a surprisingly large number (seven trials; 20%) have been withdrawn, suspended, or terminated—more than twice the rate seen for clinical studies using non-fetal stem cells.[1098] Together, these 42 fetal or embryonic stem-cell studies account for only 0.01% of all ongoing clinical trials. Clearly, the vast majority of scientists and physicians developing new treatments for human disease do not rely on either human fetal tissue or stem-cell lines derived from human fetuses.

Importantly, fetal tissue has been used in clinical research since the 1920s,[1099] yet in nearly 100 years of unrestricted research, *not a single clinical treatment has been developed from human fetal tissue*. Even worse, there are currently only a handful of studies investigating the use of fetal tissue or fetal-derived cells, most of which are in very early (phase I) clinical trials that have not yet shown any benefit to patients. Fetal tissue research has had ample time to prove itself clinically useful and has failed to do so. The evidence clearly indicates that *fetal tissue research is outdated technology that is largely ignored in by the clinical research enterprise because it has shown no benefit to patients.*

b) Non-fetal stem cells have consistently shown much greater clinical promise than fetal stem cells

As noted above, human fetal tissue has been the subject of clinical and scientific research since the 1920s, yet in modern research, fetal tissue is primarily used as a source of stem and progenitor cells. Similar cells exist in multiple adult and birth-related tissues, yet they have only recently become the subject of active clinical investigation. For example, while scientists appreciated the existence of stem cells in bone marrow as early as the 1930s,[1100] bone marrow

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[1097] Based on the Clinical Trials website; Queried 11/22/2016; www.clinicaltrials.gov.

[1098] Overall, 8.1% of all studies listed in the Clinical Trials database have been terminated, suspended, or withdrawn (18,868 of 230, 631 as of 11/22/2016). A slightly higher number of studies involving non-fetal stem cells have been prematurely terminated (635 of 5805; 10.9%). Studies can be ended prematurely for a number of reasons, including insufficient recruitment of patients, futility (no positive results), clear benefit to patients or harm to patients. A recent analysis indicates that three factors (insufficient recruitment, futility and harm) account for 82% of premature terminations. *See* Premature trial discontinuation often not accurately reflected in registries: comparison of registry records with publications. Alturki R, Schandelmaier S, Olu KK, von Niederhäusern B, Agarwal A, Frei R, Bhatnagar N, Hooft L, von Elm E, Briel M. J Clin Epidemiol. 2016 Sep 7. pii: S0895-4356(16)30403-6

[1099] Op cit. Hurst AF, *Addison's Disease, 1922.*

[1100] Based on the PubMed database, the first paper with the phrase "stem cell" in the title or abstract was published in 1932; The production of osteogenic sarcomata and the effects on lymph nodes and bone marrow of intravenous infections of radium chloride and mesothorium in rabbits. Sabin FR, Doan CA, Forkner CE. J Exp Med. 1932 Jul 31;56(2):267-89.

from an unrelated donor was not used for a medical transplant until 1968,[1101] more than four decades after the first fetal tissue transplant. The first non-fetal stem cells from tissue other than bone marrow (satellite cells from muscle) were not isolated until 1986.[1102] Finally, multi-lineage progenitor cells were first isolated from adult adipose tissue in 2001,[1103] and these cells proved to be so medically promising, they were used in clinical trials a mere four years later.[1104] Despite the relatively recent isolation of non-fetal stem cells from bone marrow, fat and other tissues, they are currently being tested in over 5,800 clinical trials for a wide range of human disease, including diabetes, Parkinson's, multiple sclerosis, heart disease and cancer. Hundreds of studies using non-fetal stem cells have already advanced to phase II and phase III trials because they have shown clear benefit to patients.[1105]

c) Conclusion

In over 100 years of unrestricted research, fetal tissue has not proven to be useful for treating human disease. In contrast, although stem and progenitor cells from non-fetal tissues have only recently been discovered, they have rapidly yielded clinical treatments with *proven benefit to patients*. The alarmist claims that restrictions on human fetal tissue research would somehow delay or prevent the development of cures are entirely unfounded.

7. Assertions that human fetal tissue is required for production of humanized mice that provide a model for human diseases with a restricted host range

Several universities (Baylor, Columbia, Dartmouth, Harvard, Hopkins, OHSU, Rockefeller, UCLA, UIC, UMN, UWM) claim that human fetal tissue is necessary to create "humanized mice" disease models. In the most extreme example of this research model, human fetal progenitors from blood, liver, and thymus are used to create a "BLT" mouse that reconstitutes many aspects of the immature human immune system.

However, humanized mice can be produced using a variety of more mature tissues, including progenitors from adult peripheral blood and from umbilical cord.[1106] Different methods of generating humanized mice have both advantages and disadvantages, with no single method being clearly superior.[1107] While there may be some scientific advantages to the use of human

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[1101] Gatti RA, Meuwissen HJ, Allen HD, et al. Immunological reconstitution of sex-linked lymphopenic immunological deficiency. Lancet. 1968 Dec 28. 2(7583):1366-9.

[1102] Bischoff R. 1986. Proliferation of muscle satellite cells on intact myofibers in culture. Dev Biol. 115:129–139.

[1103] Zuk, P.A., Zhu, M., Mizuno, H., Huang, J., Futrell, J.W., Katz, A.J., Benhaim, P., Lorenz, H.P., and Hedrick, M.H. (2001). Multilineage cells from human adipose tissue: implications for cell based therapies. Tissue Eng 7, 211-228.

[1104] García-Olmo D, García-Arranz M, Herreros D, Pascual I, Peiro C, Rodríguez-Montes JA. A phase I clinical trial of the treatment of Crohn's fistula by adipose mesenchymal stem cell transplantation. Dis Colon Rectum. 2005;48(7):1416–1423.

[1105] A query of Clinical Trials website returns over 700 phase II and phase III trials involving non-fetal stem cells. Queried 10/28/2016; www.clinicaltrials.gov.

[1106] Reviewed in: Increasing hematopoietic stem cell yield to develop mice with human immune systems. Biancotti JC, Town T. Biomed Res Int. 2013;2013:740892.

[1107] Humanized mice for immune system investigation: progress, promise and challenges. Shultz LD, Brehm MA, Garcia-Martinez JV, Greiner DL. Nat Rev Immunol. 2012 Nov;12(11):786-98.; Improvements and Limitations of

fetal tissue in some experimental settings, fetal tissue is clearly not "required" for production of humanized mice. Moreover, this is a rapidly evolving technology, with many avenues as yet unexplored. For example, it is unclear whether fetal liver and thymus are required to produce "BLT" mice. Recent work indicates thymic tissue is functional throughout adult life, [1108] and postnatal thymic tissue has been used to reconstitute immune function in human patients,[1109] strongly suggesting that human fetal thymus may not be required for the BLT-mouse model.

8. Assertions that human fetal tissue is required to "validate" scientific findings obtained with human embryonic stem cells (hESCs) or human induced pluripotent stem cells (hiPSCs)

Several universities (Columbia, UCLA, Penn, and Yale) make this assertion, but it is unsupported by the scientific literature. Only a tiny fraction of all papers indexed in PubMed on the topic of cellular reprogramming also examine fetal tissue. Moreover, the use of iPSCs has grown dramatically since this technology was pioneered in 2007,[1110] yet despite the claim that human fetal tissue is required to "validate" iPSCs, there has been no corresponding growth in the use of human fetal tissue over this period.

Although the same assertions have been put forward by multiple institutions and individuals, these claims have no factual support. To date, the Panel has received *no evidence from scientific societies, medical societies, research universities, or individual scientists supporting the conclusion that human fetal tissue research provides unique scientific information or that this research is important for the development of new treatments for human disease.*

C. Response to the claim that "The Select Panel Has Thwarted Life-Saving Research"

The Minority report of the House Select Investigative Panel, dated December 5, 2016 (hereafter, "the Minority Report"), boldly states that "Select Panel Republicans have conducted an end-to-end attack on fetal tissue donation and research" (p. 12) and have "roundly rejected or ignored" the evidence for the value of this research, concluding:

> In reality, the Panel has received ***overwhelming evidence*** of the indispensable role that fetal tissue research plays in advancing our understanding and treatment of a staggering array of conditions that

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Humanized Mouse Models for HIV Research: NIH/NIAID "Meet the Experts" 2015 Workshop Summary. Akkina R, Allam A, Balazs AB, Blankson JN, Burnett JC, Casares S, Garcia JV, Hasenkrug KJ, Kashanchi F, Kitchen SG, Klein F, Kumar P, Luster AD, Poluektova LY, Rao M, Sanders-Beer BE, Shultz LD, Zack JA. AIDS Res Hum Retroviruses. 2016 Feb;32(2):109-19.

[1108] The role of the thymus in immune reconstitution in aging, bone marrow transplantation, and HIV-1 infection. Haynes BF, Markert ML, Sempowski GD, Patel DD, Hale LP. Annu Rev Immunol. 2000;18:529-60.

[1109] Transplantation of thymus tissue in complete DiGeorge syndrome. Markert ML, Boeck A, Hale LP, Kloster AL, McLaughlin TM, Batchvarova MN, Douek DC, Koup RA, Kostyu DD, Ward FE, Rice HE, Mahaffey SM, Schiff SE, Buckley RH, Haynes BF. N Engl J Med. 1999 Oct 14;341(16):1180-9.

[1110] Human embryonic and induced pluripotent stem cell research trends: complementation and diversification of the field. Kobold S, Guhr A, Kurtz A, Löser P. Stem Cell Reports. 2015 May 12;4(5):914-25.

> afflict millions of people in this country and throughout the world. [emphasis added]

In support of this conclusion, the Minority Report identifies 10 medical conditions that it claims have benefited from human fetal tissue research. Yet for each of these conditions, the "overwhelming evidence" amounts to nothing more than unsupported assertions made by universities, scientific societies and individual scientists that have been uncritically repeated in the Minority Report, seemingly as an act of blind faith in scientific "authorities."

While appealing to authority can sometimes be a valid way to formulate an opinion, the views of individual scientists who personally conduct human fetal tissue research (and of the institutions that employ such individuals) are clearly subject to conflict of interest. When such views are also unaccompanied by any form of factual evidence, they have even less credibility. Yet when such personal opinions are also *manifestly contradicted by the available evidence*, they must (at minimum) be dismissed as groundless, and (at worst) be seen as a deliberate attempt to distort the facts out of self-interest or ideological conviction.

We have already addressed in detail the false and misleading arguments put forward in letters to the panel (Chapter 9.B). Here, we specifically address the claims made in the Minority Report and demonstrate that publicly available evidence[1111] **clearly establishes the claims made in the report are false.** Below, we discuss each of these claims in light of the evidence and conclude by presenting factual data on the use of fetal tissue in NIH-funded disease research, FDA-approved clinical trials and in the peer-reviewed scientific literature.

1. Alzheimer's

The Minority Report begins by solemnly reminding us that Alzheimer's is a serious disease (p. 13). We agree. However, the report uncritically repeats the assertion made by Dr. Lawrence Goldstein that fetal tissue is the "gold standard" for Alzheimer's research. As noted in Chapter 9.B.5 of this report, the facts simply do not support Dr. Goldstein's opinion on this matter or justify the unquestioning faith the Minority Report appears to have placed in the veracity of his assertion. In reality, of the 1300 research grants investigating Alzheimer's awarded in 2014 and the over 1900 ongoing clinical trials testing possible treatments for Alzheimer's, *not a single one uses fetal tissue*.[1112] While Dr. Goldstein may personally believe human fetal tissue is "the gold standard" for research, the vast majority of his scientific colleagues, as well as the NIH and the FDA clearly do not share this opinion.

[1111] Including: the funded grant database maintained by the National Institutes of Health (www.projectreporter.nih.gov), the clinical trials database maintained by the NIH and the Food and Drug Administration (www.clinicaltrials.gov), and the PubMed database of peer-reviewed scientific research maintained by the NIH and the National Library of Medicine (www.ncbi.nlm.nih.gov/pubmed).

[1112] A search of the NIH database of funded research (https://projectreporter.nih.gov) for 2014 using the NIH spending categories "Alzheimer's Disease" and "Human Fetal Tissue" returned two projects: one "core facility" (P50 award) that does not support a specific research program and one award that mentions Alzheimer's Disease, but is in fact focused on Down syndrome. A search of the clinical trials database (www.clinicaltrials.gov) for the term "fetal" and the medical condition "Alzheimer's" returned no studies.

2. Amyotrophic lateral sclerosis (ALS)

The Minority Report also reminds us that ALS is a serious disease (p. 13), and again, we agree. Just as for Alzheimer's, the report uncritically repeats assertions made by Johns Hopkins University and UCLA that fetal research is somehow important for developing a cure for ALS. Yet in reality, there is no evidence to support this assertion. Of the 360 ongoing clinical trials for ALS, only a single study involves transplantation of human fetal tissue (NCT01640067). This trial, completed in December of 2015, was an early, "phase I" study that has thus far neither advanced to a phase II trial nor published any results. Thus, despite the hyperbolic claim that "fetal tissue has already resulted in promising developments with regards to potential ALS treatments" (p. 14), there are no clinical findings in support of this claim.

The study of a new drug for ALS noted by Johns Hopkins is most likely to be the phase I trial of GM604, or Genervon's Master Regulator 604 (NCT01854294). The Minority Report repeats Johns Hopkins' glowing characterization of this research as "so promising for a potential ALS treatment that the FDA has approved an investigational new drug application for early stage clinical trials" (p. 14). Yet a comprehensive report on the GM604 trial by ALSUntangled (www.alsuntangled.com),[1113] a patient advocacy group and information resource, assigns this trial three "D" scores (the second lowest) and two "U" or "unranked" scores—indicating that there is insufficient information to make a valid judgment regarding the quality of the trial. They note that there is only a single "possibly relevant" publication using this drug in a mouse model of stroke (not ALS), with no peer-reviewed studies supporting the many claims made regarding GM604 on the Genervon web site. The report concludes:

> At this time, ALSUntangled finds no independently verifiable data supporting the efficacy or even the safety of GM604 in patients with ALS. We believe that independent peer review and replications are fundamentals of good science.

The Republican members of the Panel agree.

3. Diabetes Mellitus (DM)

Once again, the Minority Report reminds us that Diabetes is also a serious disease (p. 14). The report repeats the assertions of Harvard and Johns Hopkins Universities that fetal tissue is important for the study of DM and the complications of this disease, including diabetic retinopathy. Yet there is a difference between *assertion* and *evidence*. Not only do Harvard and Johns Hopkins fail to report any evidence in support of their assertions; the objective facts largely contradict their conclusion. For example, in 2014, the NIH funded 2,332 research grants on the topic of diabetes and related diseases, and only 4 of these grants (less than 0.2%) involve human fetal tissue; one "exploratory" (R21) grant, a Postdoctoral fellowship award (F32) and two investigator initiated (R01) grants.[1114] While these projects report modest scientific results (an average of 1.2 scientific papers/grant/year), they are clearly not at the forefront of the field in

[1113] ALSUntangled No. 34: GM604. Amyotroph Lateral Scler Frontotemporal Degener. 2016 Oct - Nov;17(7-8):617-621.
[1114] Based on the NIH database: https://projectreporter.nih.gov/.

terms of productivity or impact. Based on the actual evidence, it is hard to see how the Minority Report's claim that human fetal tissue research makes a significant impact on DM is justified.

Similarly, of the *11,398 current clinical trials for childhood diabetes*, only one (NCT02239354) involves human fetal tissue.[1115] Similar to the GM604 trial discussed above, this DM study is an early, phase I trial with no reported results, and therefore the "promise" (or lack of promise) of this approach cannot be evaluated. However, the fact that fetal tissue contributes to only a single trial out of over 11-thousand clearly indicates that the overwhelming majority of physicians and scientists working to relieve diabetes patients "of the daily finger pricks and insulin injections they need to stay alive" (p. 14) simply do not share the opinion voiced by Harvard and Johns Hopkins that fetal tissue is important for basic and clinical research into this disease.

4. HIV/AIDS

The Minority Report quotes three institutions (the University of Minnesota, Oregon Health and Science University, and the International Society for Stem Cell Research), all of which assert that fetal tissue research has provided significant benefit to HIV patients. It also repeats an assertion made by Dr. Brooks Jackson of the University of Minnesota that fetal tissue was "critical in my research to develop an intervention to prevent mother-to-child transmission of HIV. That research alone has saved over 1 million infants in the last ten years while also reducing elective abortion in HIV positive women by more than half in this country." Dr. Jackson makes this assertion despite the fact that a query of the PubMed database[1116] does not return a single paper using fetal tissue that lists him as an author.

It is possible Dr. Jackson is merely asserting that human fetal tissue research contributed in some general way to HIV research, while his own research is responsible for saving over one million infants. Yet if this claim refers to the United States, it is *mathematically impossible*. The Centers for Disease Control and Prevention (CDC) report that "women represent 20%, (246,372) of the estimated 1,210,835 cumulative AIDS diagnoses in the United States from the beginning of the epidemic through the end of 2014."[1117] Even if every single woman in this country who had ever been infected with HIV had also been pregnant and had further been the beneficiary of Dr. Jackson's intervention, there are simply not enough HIV-positive women to have "saved over 1 million infant lives over the last 10 years" by preventing transmission of the virus from women to their children.

Alternatively, Dr. Jackson may be asserting that his research in other countries (presumably the HIVNET 012 clinical trial in Africa) has "alone" saved 1 million infants. It is true that global efforts to reduce HIV transmission from mothers to children have improved outcomes for women and children worldwide. AIDS.gov reports that there are approximately 1.8 million children living with HIV worldwide. In 2015, 77% of HIV-positive pregnant women had access to antiretroviral medicines to prevent transmission to their babies, with new HIV infections among children declining by 50% since 2010. This is an encouraging trend, yet there is no clear evidence that human fetal tissue was "critical" to either Dr. Jackson's research or to

[1115] Based on the Clinical trials database: www.clinicaltrials.gov.
[1116] https://www.ncbi.nlm.nih.gov/pubmed.
[1117] CDC, HIV Among Women, https://cdc.gov/hiv/group/gender/women/.

the development of antiretroviral drug treatments for HIV. Moreover, it is disingenuous to claim that the research of a single investigator has been responsible for the benefits provided by a global effort to combat HIV that (in the U.S. alone) has involved:

The Department of State[1118]
The Department of Health and Human Services[1119]
The Centers for Disease Control[1120]
The Food and Drug Administration[1121]
The Health Resources and Services Administration[1122]
The National Institutes of Health[1123]
The Substance Abuse and Mental Health Service Administration[1124]
The Department of Commerce[1125]
The Department of Defense[1126]
The Department of Labor[1127]
The Peace Corps[1128]
The U.S. Agency for International Development[1129]
27,398 NIH research grants on HIV/AIDS in the last five years[1130]
7946 ongoing clinical trials to treat HIV/AIDS[1131]

5. Infant and Childhood Leukemia

The Minority Report quotes two institutions (UCLA and CHOP) who assert that fetal tissue is important for treating childhood leukemia. Yet, as we have already noted, assertion is not evidence, and the facts do not support this assertion. Between 2010 and 2014, the NIH funded 887 grants on childhood leukemia, and *not a single project used human fetal tissue*. Similarly, of the 750 ongoing clinical trials for childhood leukemia, *not a single one involves fetal tissue*. While individual researchers and their institutions may "believe" without factual support that fetal tissue is important for the study and treatment of this disease, *it is not used for any successful, NIH-funded research programs or for any clinical trials designed to cure patients of childhood leukemia.*

[1118] http://www.pepfar.gov/about/agencies/c19390.htm.
[1119] http://www.pepfar.gov/about/agencies/c19401.htm.
[1120] http://www.cdc.gov/globalhivtb/index.html.
[1121] http://www.fda.gov/internationalprograms/pepfar/default.htm.
[1122] http://hab.hrsa.gov/global-hivaids-program.
[1123] https://aidsinfo.nih.gov/.
[1124] http://www.samhsa.gov/hiv-aids-viral-hepatitis.
[1125] http://www.pepfar.gov/about/agencies/c19398.htm.
[1126] http://www.pepfar.gov/about/agencies/c19397.htm.
[1127] http://www.pepfar.gov/about/agencies/c19400.htm.
[1128] http://www.pepfar.gov/about/agencies/c19402.htm.
[1129] https://www.usaid.gov/what-we-do/global-health/hiv-and-aids.
[1130] Grants on the topic of HIV/AIDS awarded between 2011-2015 (https://projectreporter.nih.gov).
[1131] www.clinicaltrials.gov.

6. Age-related Macular degeneration (AMD)

Harvard University and the University of Michigan assert that fetal tissue is important for the study of AMD *and adult-onset disease*. Go figure. While some researchers investigating AMD use fetal eyes, the relevance of this tissue to the disease is remote, especially given the many well-documented differences between fetal and adult neural tissue.[1132]

7. Preterm birth

The University of Illinois at Chicago reports that fetal tissue is "essential" for studying premature birth, but (again) this claim is difficult to reconcile with the facts. In 2014, the NIH funded 337 grants in the general area of "conditions affecting embryonic and fetal periods," and only one award employed human fetal tissue. Moreover, over a period of nine years, this project has only been modestly productive, yielding 11 papers, only 9 of which address basic biology and none of which appeared in top-ranked scientific journals. How this very modest level of productivity constitutes an "essential" contribution to the field is hard to imagine.

8. Spinal cord injury

The Minority Report again quotes Dr. Goldstein's assertion that research trials involving fetal tissue "are vital to pushing medical science forward" (p. 17), citing a single, phase I clinical trial using fetal-derived stem cells to treat spinal cord injury. What Dr. Goldstein fails to mention is that there are *over 900 clinical trials treating spinal cord injury*, including over 40 involving stem cells derived from adult tissue and over 100 that have advanced to phase II trials. How a single study with no published findings is "pushing medical science forward" in the wake of hundreds of promising treatments for spinal injury is hard to imagine.

9. Vaccine research

The Minority Report quotes Harvard, Yale, and the University of Wisconsin in asserting that human fetal tissue research has been vital to the development of vaccines. They falsely assert that "Panel Republicans acknowledge that the development of the polio vaccine relied on fetal tissue research," apparently having failed to read or at least failed to understand the interim report of the Republican members. As detailed above in Chapter 9.B.2-3, it is invalid to claim that vaccine research "would not have been possible without cells of fetal origin" (p. 17). This argument is as illogical as asserting, "vaccine research would not have been possible without automobiles," simply because automobiles were used by some vaccine researchers and may have facilitated research in some cases. While it is impossible to know how vaccine research might have unfolded without the use of fetal tissue, history *conclusively proves that it is entirely possible to develop vaccines without "cells of fetal origin."* For example, vaccines for Rabies, Diphtheria, Typhoid, Cholera, Plague, Tetanus, Pertussis and Bacille-Calmette-Guerin disease)

[1132] A survey of human brain transcriptome diversity at the single cell level. Darmanis S, Sloan SA, Zhang Y, Enge M, Caneda C, Shuer LM, Hayden Gephart MG, Barres BA, Quake SR. Proc Natl Acad Sci U S A. 2015 Jun 9;112(23):7285-90.

were all developed in the 1800s and early 1900s, well before the first use of fetal tissue in research. It is also an indisputable fact that the vaccines for Polio, Measles, Mumps and (the first) vaccine for Rubella were all developed using animal cell culture. Finally, of the nearly 75 vaccine formulations approved for use in the United States, *not a single vaccine is produced using fetal tissue* (see Exhibit 9.3).

10. Zika research

Again quoting the opinions of individuals and organizations, the Minority Report asserts that "fetal tissue is most needed in circumstances such as the Zika virus" (p. 18). Yet the published literature in this area simply does not support this assertion. As noted in Chapter 9.B.4 of this report, human fetal tissue research is not making a strong contribution to Zika research, with the major advances published in the most respected journals involving cell culture and animal models. Moreover, current clinical trials for a virus that causes brain defects very similar to Zika (the Cytomegalovirus) have clearly not relied on human fetal tissue research.

11. Objective Data on the contribution of fetal tissue to basic research, clinical research, and peer-reviewed scientific publications

It could possibly be the case that the institutions the Minority Report relied on simply erred in identifying diseases that benefit from human fetal tissue research; *i.e.*, if the institutions had focused on diseases arising during fetal life and/or affecting infants and children, human fetal tissue might play a greater role in this research. However, this is also not the case. Even for diseases arising during fetal life, human fetal tissue research plays little or no role in basic science investigations or clinical investigations and makes only a trivial contribution to the scientific literature (Table 1).

Below we present data on 1) grants that the NIH lists under specific disease funding areas that also use human fetal tissue, 2) clinical trials for specific diseases that also use human fetal tissue (Exhibit 9.4) and 3) publications indexed in the PubMed database that include both specific disease name and the terms "fetus" and "humans" as Medical Subject Headings (MeSH).

While the data on grants and clinical trials is comprehensive, the data on publications is informative but likely to be less comprehensive. The PubMed database is large, indexing over 20 million research papers. It is impossible to examine publications in detail, and searches of this database must rely on MeSH term indexing that does not specifically identify papers using human fetal tissue for research. Consequently, some publications using fetal tissue are not likely to be identified by this search (false negatives), and some publications that are identified do not actually use fetal tissue for research (false positives).

For example, a large proportion of the papers indexed under the MeSH terms "fetus" and "preterm birth" do not utilize fetal tissue for research, but rather examine aspects of fetal physiology (heart rate, response to interventions, etc.) in an attempt to either predict or prevent preterm delivery.[1133]

[1133] *See, e.g.*, Ultrasound Measurement of the Fetal Adrenal Gland as a Predictor of Spontaneous Preterm Birth. Hoffman MK, Turan OM, Parker CB, Wapner RJ, Wing DA, Haas DM, Esplin MS, Parry S, Grobman WA, Simhan HN, Myers S, Holder TE Jr, Rumney P, Litton CG, Silver RM, Elovitz MA, Peaceman AM, Emery S, Mercer

However, the relative contribution of all types of fetal research, including fetal tissue

Table 1: Contribution of human fetal tissue to disease research.

Diseases Identified in the Minority Report	Grants Awarded 2015			Clinical trials			Peer Reviewed Papers		
	Fetal	Total	%	Fetal	Total	%	"Fetus"	Total	%
Alzheimer's	0	1362	0.0%	0	1956	0.0%	109	75704	0.1%
Amyotrophic lateral sclerosis	0	152	0.0%	3	360	0.8%	33	14859	0.1%
Diabetes Mellitus	6	2382	0.3%	1	14807	0.01%	1486	353110	0.4%
HIV/AIDS	74	4935	1.5%	0	7950	0.0%	372	87756	0.4%
Infant and Childhood Leukemia	0	339	0.0%	0	750	0.0%	21	1996	1.1%
Age-related Macular degeneration	5	187	2.7%	10	1371	0.7%	15	18826	0.1%
Preterm birth*	4	355	1.1%	0	3375	0.0%	503	9006	5.6%
Spinal cord injury	0	249	0.0%	8	907	0.9%	49	41461	0.1%
Vaccine research	28	2509	1.1%	0	7024	0.0%	509	280174	0.2%
Zika/Brain Disorders**	158	52338	0.3%	0	18	0.0%	6	1926	0.3%
Diseases Arising in the Fetus and/or Affecting Children	**Grants Awarded 2015**			**Current clinical trials**			**Peer Reviewed Papers**		
	Fetal	Total	%	Fetal	Total	%	"Fetus"	Total	%
Attention Deficit Disorder	0	121	0.0%	0	1277	0.0%	23	23079	0.1%
Autism	2	506	0.4%	0	741	0.0%	43	17711	0.2%
Batten Disease	0	15	0.0%	0	23	0.0%	7	1761	0.4%
Epilepsy	2	397	0.5%	0	1404	0.0%	289	141397	0.2%
Hydrocephalus	0	15	0.0%	0	135	0.0%	275	21192	1.3%
Intellectual disabilities	10	1025	1.0%	0	541	0.0%	1255	86516	1.5%
Pediatric AIDS	0	467	0.0%	0	350	0.0%	8	1586	0.5%
Pediatric cancer	0	760	0.0%	0	1642	0.0%	302	56854	0.5%
Spinal muscular atrophy	0	34	0.0%	0	157	0.0%	15	1050	1.4%
Sudden Infant Death Syndrome	1	31	3.2%	0	89	0.0%	78	7094	1.1%

Grant data is from the NIH project reporter database. Clinical data is from the clinical trials database. Publication data is from the PubMed database (queried for disease name, "fetus" and "humans" as MeSH terms.

* The NIH does not have a spending category for preterm birth; grant data shown is for the broader category "Conditions affecting the embryonic and fetal periods," many of which result in preterm birth or fetal demise.

**The NIH does not have a spending category for Zika research; grant data shown is for the broader category "Brain Disorders," which includes a wide range of medical conditions.

research, to various diseases can be reasonably inferred from this data, and in all cases, *fetal tissue makes a tiny contribution to disease research, if it contributes at all.*

BM,Koch MA, Saade GR; Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be (nuMoM2b) Network.. Obstet Gynecol. 2016 Apr;127(4):726-34. Intra-Amniotic Administration of HMGB1 Induces Spontaneous Preterm Labor and Birth. Gomez-Lopez N, Romero R, Plazyo O, Panaitescu B, Furcron AE, Miller D, Roumayah T, Flom E, Hassan SS. Am J Reprod Immunol. 2016 Jan;75(1):3-7.

12. Conclusion

The assertions of the Minority Report are undocumented and unsupported by any of the publicly available evidence. Rather, this evidence clearly indicates that for all of the diseases held up as examples by the Minority Report, human fetal tissue makes little or no contribution to either research, clinical trials or the peer-reviewed scientific literature. ***There is no "overwhelming evidence" for the value of human fetal tissue research. In fact, there is no evidence at all.*** There is only what appears to be self-interested assertion from individuals and institutions engaged in human fetal tissue research that the Minority Report has naively accepted as "fact."

D. Analysis of currently funded long-standing human fetal-tissue research.

1. Goals of This Analysis

Many assertions have been made regarding the role of human fetal tissue in modern biomedical research, but to date, no factual evidence in support of these assertions has been provided. Moreover, publicly available evidence directly contradicts the claims made by universities, scientific societies and professional medical associations that are repeated in the Minority Report. We have presented considerable evidence that contradicts these claims. However, the data discussed thus far does not directly address three central questions regarding human fetal tissue research:

a. How many research projects rely on human fetal tissue?
b. How productive is human fetal tissue research, compared to non-fetal tissue research?
c. What is the impact of human fetal tissue research on the field, compared to non-fetal research; *i.e.*, how "important" is fetal research for the advance of science and medicine?

To answer these critical questions, the House Select Investigative Panel elected to conduct a neutral and objective examination of current human fetal tissue research.

2. Criterion for Grant Selection

It is important to note that grants utilizing human fetal tissue were not evaluated by the Panel for either the quality of the research or the competence of the investigator; *i.e., it was assumed that the process of peer review is sufficient to identify meritorious research and successful scientists.* Grants were examined only to determine the precise use of human fetal tissue and the impact of this research on the literature. To achieve these goals, grants were selected from the National Institutes of Health (NIH) grant database (https://projectreporter.nih.gov), using the following criteria.

a. To determine the use of human fetal tissue over an extended period, grants funded by the NIH over the last five years (2010-2014) were examined. A total of 329 grants using human fetal tissue were awarded during this period. **This represents approximately 0.2% of the total NIH-funded grant portfolio for these years.**

b. In order to determine the productivity and the impact of successful research programs involving human fetal tissue, established grants (*i.e.*, grants that had undergone competitive renewal and had been funded for 10 or more years) were further evaluated.
c. Several grant mechanisms were excluded from detailed analysis for the following reasons:
    i. Grants that are not directly responsible for generating scientific findings were not analyzed (*i.e.*, grants funding institutional "core" facilities or centers; P50, P30, PN2, R24, U54 and P01 cores).
    ii. Intramural grants to NIH researchers (ZIA) were excluded because they are awarded using criteria specific to internal NIH programs and therefore cannot be directly compared to external research grants.

3. Grant Classification

These criteria identified a total of 36, long-standing grants to individual researchers. A detailed inspection determined that only 34 of these projects involved primary human fetal tissue. These 34 projects were examined by a scientific reviewer to determine the proposed use of human fetal tissue relative to the research questions, as defined by the investigators themselves. The 34 grants investigate a range of scientific topics, but most address either basic mechanisms of biologic function or adult-onset disease. For example, twelve of the 34 grants investigate conditions arising in adults, while 15 are focused on basic biological processes that occur at all stages of life. Only a minority were focused on processes occurring during fetal life. Based on the research questions and the use of human fetal tissue proposed by the investigators, grants using fetal tissue were divided into three classes.

a. **Class 1:** Fetal tissue is required for the proposed study. There are no reasonable alternatives.
b. **Class 2:** Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist.
c. **Class 3:** Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist. In some cases, postnatal tissue is more relevant to the scientific question.

Of the 34 long-standing grants examined, 8 (approximately 24%) require human fetal tissue to accomplish the aims of the grant (*i.e.*, no reasonable alternatives exist). For 5 grants (approximately 15%), the use of human fetal tissue provides some advantage in terms of efficiency and/or relevance to human disease. However, these advantages are not critical to accomplish the goals of the proposed research, and reasonable alternatives exist; *i.e.*, the investigators themselves proposed multiple means to accomplish the same goals, most of which did not require human fetal tissue. For the remaining 21 grants (approximately 62%), human fetal tissue is not required to accomplish the goals of the proposed research, there are no advantages to the use of human fetal tissue, and superior alternatives exist. The nature of the studies and the proposed use of human fetal tissue are summarized in Exhibit 9.5, The Grant Classification Table. NB: To avoid any privacy concerns, the names of the grants and of the investigators that were included in the public database have been redacted.

4. Class 1 Grant Analysis

Eight Class 1 grants were identified. *This represents approximately 0.002% of the NIH research portfolio for this period (2010-14)*; *i.e.*, only 2 grants out of 100,000 are both long-standing and require human fetal tissue.

To obtain information on the relative productivity and impact of Class 1 grants, the publicly available information was further analyzed. The NIH database of funded research includes detailed information on publications resulting from each grant. Within the scientific profession, one of the most widely accepted means of determining the impact of a specific research paper is the number of citations that are made to that paper in the literature (*i.e.*, the "citation index"). Therefore, to determine the productivity and impact of human fetal tissue research, we examined both the number of papers resulting from each grant and the number of citations made to those papers by other researchers in the field.

Several factors must be taken into consideration when comparing research productivity and impact across different research groups and different scientific fields. First, the number of papers published varies considerably in different areas of research, depending on the amount of time necessary to conduct specific kinds of scientific investigations. Moreover, laboratories at well-endowed institutions can produce papers more rapidly, due to superior institutional support and facilities. Therefore, simply comparing the number of publications produced by different laboratories at different institutions can sometimes be misleading.

Similarly, the number of citations a specific paper receives can vary quite a bit from field to field. For example, some areas of research involve a large number of investigators, and papers in such areas receive a greater number of citations compared to papers of similar quality in research areas with fewer investigators.

To control for these factors, the productivity and relative impact of human fetal tissue research was determined by comparing publications that either did or did not involve human fetal tissue that were produced by the same research groups. A detailed examination of all publications resulting from the eight Class 1 grants identified above determined that seven of these research groups conducted both fetal and non-fetal research (as determined by a knowledgeable scientific reviewer), and therefore the productivity and impact of fetal and non-fetal research could be directly compared, with all other factors remaining constant.

A final factor taken into consideration was that the number of citations a paper receives is influenced by the date of publication in both positive and negative ways. Papers published earlier have more time to accumulate citations than recently published papers of similar quality. Conversely, papers published long ago using outdated technology tend not to be cited in the current literature unless they are of particular historic significance—regardless of the overall quality and impact of the research at the time of publication. Therefore, to fairly compare fetal and non-fetal research from the same laboratories, we considered papers published over the last 15 years (*i.e.*, from 2001 onward), ending with the most recently published paper involving human fetal tissue.

5. Productivity of Human Fetal Tissue Research and Impact on the Field

The number of citations for every publication listed in the NIH database for Class 1 grants was determined.[1134] From the seven Class 1 research groups that published both fetal and non-fetal research in this period, **there were 2.3x more publications not involving human fetal tissue** (Table 2). This indicates that within the same scientific discipline and the same research laboratory, human fetal tissue research is far less productive than research not involving human fetal tissue.

Table 2: Class 1 Grant productivity and impact.

	Fetal	**Non-Fetal**
Productivity: Average number of papers	74	167
Impact: Average number of citations/paper	36	75

Similarly, **publications that did not involve fetal tissue received an average of 2.1x more citations/paper, compared to publications involving fetal tissue from the same research group.** This strongly suggests that human fetal tissue research is of lower quality compared to studies involving fetal tissue and has significantly less impact on the field.

Human fetal tissue is currently used by a very small number of scientists, representing less than 0.2% of the total NIH research portfolio. Detailed analysis of how human fetal tissue is used in 34 long-standing, successful research programs has determined that fetal tissue is actually required for only approximately 24% of these grants. For the remaining 76%, there are reasonable alternatives to the use of human fetal tissue and, in the majority of cases, these alternatives are superior scientific models. Based on these percentages, it is estimated that of the current 329 NIH-funded grants using human fetal tissue, only approximately 79 (or 0.08% of the 83,592 active projects), actually require the use of human fetal tissue. Thus, despite the repeated claim that human fetal tissue is "necessary" for modern biomedical research, only a tiny fraction of NIH funded research actually requires human fetal tissue. Moreover, even in cases where use of human fetal tissue is warranted (*i.e.*, Class 1 grants), this analysis indicates that **human fetal tissue research is less productive and has lower impact on the field, compared to studies from the same laboratories that do not involve human fetal tissue.**

In Conclusion: This analysis strongly indicates that, in contrast to repeated assertions, human fetal tissue research is an outdated and unproductive area of research that does not make a

[1134] Based on the citations identified using the "Google Scholar" search engine that is employed by the NIH: https://scholar.google.com/.

strong impact on the field. In over 100 years of unrestricted investigation, human fetal tissue research has had ample time to prove useful, yet it has failed to do so:

- Fetal tissue HAS NOT produced a single medical treatment.
- Fetal tissue WAS NOT used to cure polio, mumps, and measles.
- Fetal tissue IS NOT used for modern vaccine production or research.
- Fetal tissue IS NOT critical to study Zika or other diseases affecting brain development.
- Fetal tissue IS NOT required for the overwhelming majority of current research.
- Fetal tissue research is LESS PRODUCTIVE and has LOWER IMPACT when compared to non-fetal tissue research.

E. Recommendations for improving access to ethical and appropriate scientific models

The House Select Investigative Panel is firmly committed to supporting scientific research and helping it to advance as rapidly as possible towards effective and ethical treatments for human disease. Our detailed examination of how fetal tissue is currently used in successful, long-standing research programs (Chapter 9.D.3) revealed that in a surprising number of cases, human fetal tissue is not the most appropriate scientific model for the proposed experiments. For example, a number of grants focused on *adult-onset* neurological conditions employ human fetal neurons as a disease model, despite the well-known differences between fetal and adult neural cells.[1135] In some cases, investigators indicate that the choice of fetal tissue is dictated by economic reasons, including the cost and/or inconvenience of obtaining appropriate adult tissue (see Exhibit 9.5). Whether tissue procurement companies have artificially created a market for human fetal tissue by making diverse human fetal tissues readily available to researchers is difficult to determine. However, there are limited commercial options for obtaining living adult tissue and cells for research, and many companies providing this service focus on a limited number of cell types (primarily cells from blood). The difficulty and expense of obtaining appropriate adult tissue for research is likely to be a factor in the decision to use less scientifically relevant human fetal tissue that is readily available through tissue procurement companies.

Ideally, decisions about which experimental model to use for the study of a specific medical condition should be driven by scientific criteria, not by issues of convenience or cost. Here we make four recommendations for improving access to appropriate scientific models, including human fetal tissue when warranted, in order to promote the advance of science and the development of novel therapies.

1. Background for Recommendation 1: Establishing an ethically and scientifically superior source of human fetal tissue

Stem and progenitor cells present in developing human tissues have tremendous potential to expand scientific knowledge and treat human disease. Yet advances in both medicine and science have been limited by the lack of a consistent and high-quality source of donated human

[1135] A survey of human brain transcriptome diversity at the single cell level. Darmanis S, Sloan SA, Zhang Y, Enge M, Caneda C, Shuer LM, Hayden Gephart MG, Barres BA, Quake SR. Proc Natl Acad Sci U S A. 2015 Jun 9;112(23):7285-90.

cells. The current model of obtaining human cells and tissues from legal abortion is inadequate for three inherent reasons: 1) abortions do not represent the full range of human development and typically do not take place during periods where the most clinically relevant cells are present; 2) during an abortion, cells cannot be obtained in a sterile manner, and therefore these cells cannot be used clinically or in many research applications; and 3) serious ethical objections to abortion are likely to persist, making abortion an unreliable and inconsistent source of human cells.

In contrast, obtaining cadaveric donation of human cells and tissues from preterm and stillborn donors avoids all three of these limitations; *i.e.*, donations can be obtained in a clinically useful state across the full spectrum of human development without significant ethical controversy. The CDC estimates there are approximately 27,000 preterm deliveries and 24,000 stillbirths each year. Currently, there is only limited ability to use donated material from preterm and stillborn infants for conventional organ transplant. Expanding the opportunities to make a potentially life-saving donation for basic and clinical research following the tragic loss of a desired infant would provide a tremendous comfort to many grieving parents.

Currently, human fetal tissue is used in a very small number of research programs funded by the National Institutes of Health: approximately 0.2% of all funded research programs. Detailed examination of a selected sample of long-standing, successful awards indicates that only a quarter critically require human fetal tissue (Chapter 9.D.3); *i.e.*, no reasonable alternatives to the use of human fetal tissue exist. However, should a consistent, high-quality and ethically uncontroversial source of human fetal tissue exist, research in this area would undoubtedly expand enormously, advancing our understanding of human development and leading to potentially life-saving discoveries.

In addition to basic research, many human diseases could potentially be addressed by treatment with stem and progenitor cells. However, such regenerative-medicine approaches are limited due to the inherent difficulty of producing cells in the laboratory that have clinically useful properties; *i.e.*, cells that can be transplanted into patients and that restore normal function without forming tumors. Natural stem and progenitor cells that arise during human development would be an ideal source of material for clinical treatment of disease, if such cells could be obtained in a clinically appropriate and ethically uncontroversial manner.

Stakeholders in the effort to provide a consistent, high-quality and ethical source of human fetal tissue for research and therapies include:

a. The scientific community: The scope of research would greatly expand and the pace of discovery accelerate if a consistent source of human cells and tissues were available.

b. The medical community: Clinical application of human stem and progenitor cells would be nearly immediate, resulting in novel treatments and cures.

c. Patients suffering from untreatable disease: The rapid advance of both basic and clinical research would provide direct benefits to patients.

d. Parents who have tragically lost a desired infant: Contributing to life-saving research and medical treatments would provide great comfort to many grieving parents.

Recommendation 1: Congress will appropriate funding to the NIH for a competitive, multi-center trial of expanding the organ-donation network to include preterm and stillborn infant donors. Cadaveric tissues and cells would be made available to qualified scientists and physicians for basic and clinical research. Material from elective termination of pregnancy would be explicitly excluded from this program, both to restrict donation to clinically useful material and to avoid ethical controversy, thereby ensuring broad, bipartisan support for this program and providing a consistent source of high-quality donations for medicine and research.

2. Background for recommendation 2: Facilitating acquisition of adult tissue

Adult tissue (from either normal subjects or from individuals with specific medical conditions) is the most scientifically appropriate model for the study of many adult-onset diseases. Unfortunately, in many cases, adult tissue is not readily available for use by the research community. Consequently, researchers focus on animal models of disease and/or supplement this work using human fetal tissue, despite the known differences between adult and fetal cells. If primary adult human tissue were more readily available to the research community, it would facilitate development of appropriate research models with far greater relevance to human disease.

Recommendation 2: The NIH will undertake a study of research demand for adult human tissue and possible methods for facilitating the acquisition of adult cells and tissues for research, without impacting the supply of transplantable human organs. Possible sources of adult tissue include material from surgical procedures and cadaveric donation of tissue/organs that are not currently used for transplantation. One potential model may be an expansion of the National Disease Research Interchange (NDRI),[1136] an NIH-supported, non-profit organ and tissue donation network that has provided surgical and cadaveric biospecimens to researchers for over thirty years.

3. Background for recommendation 3: Establishing guidelines for the use of human fetal tissue

The process of scientific grant review evaluates the overall quality of the proposed research and the appropriateness of the scientific model. However, grant reviewers are not currently asked to consider whether the use of human fetal tissue is warranted by the experimental design, and there are no guidelines for making such a determination.

The use of animals in research provides a helpful model for the use of human fetal tissue. The NIH has a detailed instruction on animal use (Guide for the Care and Use of Laboratory Animals, hereinafter "the Guide").[1137] While supporting the value of animal research, the Guide acknowledges, "The decision to use animals in research requires critical thought, judgment, and

[1136] Information about NDRI is available at http://ndriresource.org/.
[1137] National Research Council, Guide for the Care and Use of Laboratory Animals (2011), https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-use-of-laboratory-animals.pdf [hereinafter Guide].

analysis. Using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being."[1138] Two central principles governing the use of animals are *Replacement* and *Reduction*, which are defined by the Guide as follows:

> **Replacement** refers to methods that avoid using animals. The term includes absolute replacements (i.e., replacing animals with inanimate systems such as computer programs) as well as relative replacements (i.e., replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).
>
> **Reduction** involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information. This approach relies on an analysis of experimental design, applications of newer technologies, the use of appropriate statistical methods, and control of environmentally related variability in animal housing and study areas.[1139]

Similar to animal research, human fetal tissue research is controversial, with the majority of American citizens opposing the sale of human fetal body parts for research.[1140] Moreover, it is widely acknowledged that the use of human embryos/fetuses for research purposes warrants special consideration. For example, the 1994 NIH Report of the Human Embryo Research Panel produced under the Clinton administration states, "The Panel believes that because the preimplantation embryo possesses qualities requiring moral respect, research involving the ex utero preimplantation human embryo must be carefully regulated and consistently monitored."[1141] In light of the moral respect due to the human embryo/fetus, the decision to use human fetal tissue in research is also "a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human . . . well-being."[1142] Consequently, just as for animal research, the decision to use human fetal tissue "requires critical thought, judgment and analysis,"[1143] with the

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[1138] *Id.* at 4.
[1139] *Id.* at 5.
[1140] A Rasmussen poll from 2015 indicates that 25% of likely voters support the sale of human fetal tissue, while 54% are opposed and 22% are undecided (http://www.rasmussenreports.com/public_content/politics/current_events/abortion/voters_balk_at_sale_of_fetal_body_parts). A Fox News poll from 2015 indicates that voters are evenly split on the use of fetal tissue for research, with 48% approving of such research, and 47% disapproving (http://www.foxnews.com/politics/2015/08/27/fox-news-poll-views-divided-over-issues-involving-abortion.html).
[1141] National Institutes of Health, Report of the Human Embryo Research Panel, vol. 1. 1994. Bethesda MD, https://repository.library.georgetown.edu/bitstream/handle/10822/559352/human_embryo_vol_1.pdf?sequence=1&isAllowed=y.
[1142] Guide at 5.
[1143] *Id.*

principles of *Replacement* and *Reduction* being applicable to all research programs using human fetal tissue.

Rigorous application of these principles would serve to limit the use of human fetal tissue to those proposals where this tissue is in fact required for the experimental question (*i.e.*, Class 1 proposals) and would reduce the overall use of such tissue to the minimum required for obtaining valid scientific results. Application of these principles would also serve as a vehicle for "critical thought, judgment and analysis" regarding what constitutes the most appropriate scientific model for a specific research question.

Recommendation 3: The NIH will establish guidelines for the use of human fetal tissue, modeled on the guidelines for animal research that include the principles of *Replacement* and *Reduction*. The NIH will mandate that these guidelines be applied to all grants proposing the use of human fetal tissue and that funding will be contingent on the investigator demonstrating that 1) human fetal tissue is required and appropriate for the proposed experiments, 2) there are no reasonable alternatives or replacements for the use of human fetal tissue, and 3) every effort has been made to reduce the amount of human fetal tissue employed in the proposed experiments.

4. Background for recommendation 4: Assuring continued availability of funding for research that requires human fetal tissue

The analysis of the House Select Investigative Panel indicates that, for a small number of research programs, human fetal tissue is the most appropriate scientific model (Class 1 grants). For a much larger number of research programs (Class 2 and Class 3), human fetal tissue is not the most appropriate model, and alternative models are available (Chapter 9.D.3). Application of the principles of *Replacement* and *Reduction* (See Recommendation 3, above) will serve to distinguish proposals that require human fetal tissue (Class 1) from proposals that do not. Appropriate classification of proposed research is required to assure continued funding for scientifically meritorious research that requires human fetal tissue.

Recommendation 4: The NIH will adopt a three-tiered classification system for proposals involving human fetal tissue as indicated below:

a. **Class 1:** Fetal tissue is required for the proposed study. There are no reasonable alternatives. These proposals will have met all of the requirements established by the NIH guidelines outlined in Recommendation 1 and will be fully eligible for funding, based on scientific merit and NIH funding priorities.
b. **Class 2:** Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist. These proposals will have met some, but not all of the requirements established by the NIH guidelines outlined in Recommendation 1 and will be eligible for funding only under exceptional circumstances, as established by scientific merit and NIH funding priorities.
c. **Class 3:** Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist. In some cases, postnatal tissue is more relevant to

the scientific question. These proposals will have failed to meet the requirements established by the NIH guidelines outlined in Recommendation 1 and will be ineligible for NIH funding.

5. Background for recommendation 5: Federal funding for fetal tissue research

Human fetal tissue is necessary for a limited number of research programs (Class 1 grants). Currently, tissue for these projects is only available from elective termination of pregnancy. Should a program for obtaining cadaveric fetal tissue donation from preterm and stillborn infants prove effective (Recommendation 1), this would provide a consistent source of human fetal tissue that is both *scientifically* and *ethically* superior to tissue obtained from induced abortion. If this is the case, fetal tissue donation should be expanded, and public research dollars should be restricted to a source of tissue that better serves the interests of basic and clinical research while simultaneously being ethically acceptable to all American citizens.

Recommendation 5: The NIH will report to Congress on the use of parent-donated tissue from natural demise of preterm children, anticipated by Recommendation 1 above, and Congress shall appropriate funds for an expansion of this program and disallow grants funded by federal dollars to utilize human fetal tissue obtained from induced abortion.

X. Recommendations

A. Recommendations for Direct Protection of Women and Infants

The Panel discerned a hardness and callousness toward women and infants, particularly after a clinic entered into a contractual relationship with a fetal tissue procurement business. The following recommendations focus on protections for women, preborn infants, and infants born alive during abortion procedures.

1) In keeping with the principles set forth in the Belmont Report, Congress should take appropriate measures to ensure that the informed consent provisions of 42 U.S.C. § 289g-1(b) & (c) protect all mothers, regardless of whether their donations of fetal tissue or the prospective research/use of donated fetal tissue is federally funded.

2) The Panel recommends that Congress pass legislation that expands and clarifies the definition of "changing the method of abortion" to ensure that abortion providers are not modifying the care of their patients, and potentially endangering patient health, to ensure that they can procure fetal tissue.

3) The Panel recommends that Congress take appropriate measures to ensure that the Department of Health and Human Services conducts greater oversight over:

    a. The use of fraudulent and misleading consent forms.

    b. Institutional Review Boards (IRB), to avoid the "mail-order" version of IRB's.

    c. Clinics found to have violated HIPAA.

    d. The training of abortion providers and clinic employees to care for infants born alive during abortion procedures (*i.e.*, protocols for calling 911 and providing life-sustaining treatment pending transfer to a hospital).

4) The Panel recommends that Congress take appropriate measures to ensure that the United State Department of Justice allocates resources for the prosecution of persons or entities that profit from the sale of fetal tissue. Additionally, Congress should prohibit any person from crossing state lines in order to obtain fetal tissue derived from an induced abortion when the law of the state in which the person is doing business prohibits the donation of such tissue.

5) Congress should pass a law providing that if the probable gestational age of the fetus is determined to be 20 or more weeks, the physician shall make his or her best reasonable efforts to deliver the infant alive. In such cases, no health care practitioner may use

digoxin or other feticide, and no physician may dismember the fetus unless it is necessary to protect the life of the mother.[1144]

6) Congress should enact a law, and the Department of Health and Human Services should promulgate detailed regulations requiring abortion providers to establish protocols for providing emergency care to infants born alive (as defined in 1 U.S.C. § 8 (b)) during abortions or attempted abortions, pending transfer to a hospital. The regulations should require, at a minimum, that all abortion providers are trained to preserve the life and resuscitate any infant who is born alive, and that abortion facilities are adequately equipped to care for infants born alive, pending transfer to a hospital. The regulations should require the presence of a health care practitioner dedicated to caring for infants born alive and to keeping precise records on methods of abortion, stages of gestation, and instances where infants show signs of life.

7) Congress should establish criminal penalties and other enforcement mechanisms to hold abortion providers accountable who fail to provide medical attention and care to infants born alive (as defined in 1 U.S.C. § 8 (b)) during an abortion or attempted abortion. At a minimum, abortion providers must ensure that a born-alive infant receives the same degree of care that is reasonably provided to any other child born at the same gestational age, and ensure that the child is immediately transferred to a hospital.[1145]

8) Legislation should also create an office in the Department of Justice, within the Criminal Division, to ensure the enforcement of the Partial-Birth Abortion Ban Act, Born-Alive Infants Protection Act, and other measures recommended in this report.

9) Legislation should ensure that that the statutory definition of cadaver uniformly includes human fetuses.

B. Recommendations for Stewardship of Taxpayer Funds

1) The Panel found that Planned Parenthood affiliates and clinics have repeatedly neglected their fiduciary duty requiring good stewardship of federal taxpayer dollars through the following: careless management and failed compliance with Medicaid billing procedures; violating federal laws and regulations pertaining to patient consent and the privacy rights of their patients; changing the method of abortion to increase procurement of fetal tissue for which they received a per tissue payment; and a general disinterest in clinical integrity. The Panel recommends that Planned Parenthood lose all federal funding, including reimbursements for Medicaid services. Further, grants no longer available to Planned Parenthood should be awarded to healthcare providers that provide comprehensive preventive healthcare for their patients, and that do not perform abortions, except:

[1144] *See* Pain-Capable Unborn Child Protection Act, H.R. 36, 114th Cong. (2015).
[1145] *See* Born-Alive Abortion Survivors Protection Act, H.R. 3504, 114th Cong. (2015).

> if the pregnancy is the result of an act of rape or incest;
>
> or
>
> in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

2) In keeping with the joint federal-state Medicaid program, the Panel recommends that Congress pass a law explicitly permitting states to exclude abortion providers from receiving Medicaid reimbursement (in response to narrow interpretations of current law by President Obama's Administration and the Seventh and Ninth Circuits).[1146]

3) The Panel also recommends that Congress pass a law overriding the Sept. 9, 2016, administrative rule restricting states' discretion in choosing subrecipients of Title X funding. Further, the new law should explicitly prohibit the federal government from contracting with anyone other than a state or a state's designee. That way, states will have the flexibility to ensure that Title X funds are used in a manner compatible with state public policy.

4) Taxpayer funding indirectly supports the practice of abortion when it funds institutions that provide or fund abortions, or when it funds research on tissue derived from aborted infants. Consistent with this principle, Congress should prohibit federal funding of research involving tissue derived from *induced* abortions. This should be enacted to become effective after establishment of a program that would fund alternative sources of fetal tissue (*i.e.*, fetal tissue from *spontaneous* abortions (miscarriages) or stillbirths) for research. See subsection C, below.

C. Recommendations to Improve Biomedical Research

The House Select Investigative Panel is firmly committed to supporting scientific research and helping it to advance as rapidly as possible towards effective and ethical treatments for human disease. Our detailed examination of how fetal tissue is currently used in successful, long-standing research programs (Chapter 9.D.3) revealed that in a surprising number of cases, human fetal tissue is not the most appropriate scientific model for the proposed experiments. For example, a number of grants focused on *adult-onset* neurological conditions employ human fetal neurons as a disease model, despite the well-known differences between fetal and adult neural cells.[1147] In some cases, investigators indicate that the choice of fetal tissue is dictated by economic reasons, including the cost and/or inconvenience of obtaining appropriate adult tissue

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[1146] *See* Women's Public Health and Safety Act, H.R. 3495, 114th Cong. (2015).

[1147] A survey of human brain transcriptome diversity at the single cell level. Darmanis S, Sloan SA, Zhang Y, Enge M, Caneda C, Shuer LM, Hayden Gephart MG, Barres BA, Quake SR. Proc Natl Acad Sci U S A. 2015 Jun 9;112(23):7285-90

(see Exhibit 9.5). Whether tissue procurement companies have artificially created a market for human fetal tissue by making diverse human fetal tissues readily available to researchers is difficult to determine. However, there are limited commercial options for obtaining living adult tissue and cells for research, and many companies providing this service focus on a limited number of cell types (primarily cells from blood). The difficulty and expense of obtaining appropriate adult tissue for research is likely to be a factor in the decision to use less scientifically relevant human fetal tissue that is readily available through tissue procurement companies.

Ideally, decisions about which experimental model to use for the study of a specific medical condition should be driven by scientific criteria, not by issues of convenience or cost. Here we make four recommendations for improving access to appropriate scientific models, including human fetal tissue when warranted, in order to promote the advance of science and the development of novel therapies.

Background for Recommendation 1: Establishing an ethically and scientifically superior source of human fetal tissue. Stem and progenitor cells present in developing human tissues have tremendous potential to expand scientific knowledge and treat human disease. Yet advances in both medicine and science have been limited by the lack of a consistent and high-quality source of donated human cells. The current model of obtaining human cells and tissues from legal abortion is inadequate for three inherent reasons: 1) abortions do not represent the full range of human development and typically do not take place during periods where the most clinically relevant cells are present; 2) during an abortion, cells cannot be obtained in a sterile manner, and therefore these cells cannot be used clinically or in many research applications; and 3) serious ethical objections to abortion are likely to persist, making abortion an unreliable and inconsistent source of human cells.

In contrast, obtaining cadaveric donation of human cells and tissues from preterm and stillborn donors avoids all three of these limitations; i.e. donations can be obtained in a clinically useful state across the full spectrum of human development without significant ethical controversy. The CDC estimates there are approximately 27,000 preterm deliveries and 24,000 stillbirths each year. Currently, there is only limited ability to use donated material from preterm and stillborn infants for conventional organ transplant. Expanding the opportunities to make a potentially life-saving donation for basic and clinical research following the tragic loss of a desired infant would provide a tremendous comfort to many grieving parents.

Currently, human fetal tissue is used in a very small number of research programs funded by the National Institutes of Health: approximately 0.2% of all funded research programs. Detailed examination of a selected sample of long-standing, successful awards indicates that only a quarter critically require human fetal tissue (Chapter 9.D.3); *i.e.*, no reasonable alternatives to the use of human fetal tissue exist. However, should a consistent, high-quality and ethically uncontroversial source of human fetal tissue exist, research in this area would undoubtedly expand enormously, advancing our understanding of human development and leading to potentially life-saving discoveries.

In addition to basic research, many human diseases could potentially be addressed by treatment with stem and progenitor cells. However, such regenerative-medicine approaches are limited due to the inherent difficulty of producing cells in the laboratory that have clinically useful properties; *i.e.*, cells that can be transplanted into patients and that restore normal function without forming tumors. Natural stem and progenitor cells that arise during human development would be an ideal source of material for clinical treatment of disease, if such cells could be obtained in a clinically appropriate and ethically uncontroversial manner.

Stakeholders in the effort to provide a consistent, high-quality and ethical source of human fetal tissue for research and therapies include:

1. The scientific community: The scope of research would greatly expand and the pace of discovery accelerate if a consistent source of human cells and tissues were available.

2. The medical community: Clinical application of human stem and progenitor cells would be nearly immediate, resulting in novel treatments and cures.

3. Patients suffering from untreatable disease: The rapid advance of both basic and clinical research would provide direct benefits to patients.

4. Parents who have tragically lost a desired infant: Contributing to life-saving research and medical treatments would provide great comfort to many grieving parents.

Recommendation 1: Congress will appropriate funding to the NIH for a competitive, multi-center trial of expanding the organ-donation network to include preterm and stillborn infant donors. Cadaveric tissues and cells would be made available to qualified scientists and physicians for basic and clinical research. Material from elective termination of pregnancy would be explicitly excluded from this program, both to restrict donation to clinically useful material and to avoid ethical controversy, thereby ensuring broad, bipartisan support for this program and providing a consistent source of high-quality donations for medicine and research.

Background for recommendation 2: Facilitating acquisition of adult tissue. Adult tissue (from either normal subjects or from individuals with specific medical conditions) is the most scientifically appropriate model for the study of many adult-onset diseases. Unfortunately, in many cases, adult tissue is not readily available for use by the research community. Consequently, researchers focus on animal models of disease and/or supplement this work using human fetal tissue, despite the known differences between adult and fetal cells. If primary adult human tissue were more readily available to the research community, it would facilitate development of appropriate research models with far greater relevance to human disease.

Recommendation 2: The NIH will undertake a study of research demand for adult human tissue and possible methods for facilitating the acquisition of adult cells and tissues for research, without impacting the supply of transplantable human organs. Possible sources of adult tissue include material from surgical procedures and cadaveric donation of tissue/organs that are not currently used for transplantation. One potential model may be an expansion of the

National Disease Research Interchange (NDRI),[1148] an NIH-supported, non-profit organ and tissue donation network that has provided surgical and cadaveric biospecimens to researchers for over thirty years.

Background for recommendation 3: Establishing guidelines for the use of human fetal tissue. The process of scientific grant review evaluates the overall quality of the proposed research and the appropriateness of the scientific model. However, grant reviewers are not currently asked to consider whether the use of human fetal tissue is warranted by the experimental design, and there are no guidelines for making such a determination.

The use of animals in research provides a helpful model for the use of human fetal tissue. The NIH has a detailed instruction on animal use (Guide for the Care and Use of Laboratory Animals, hereinafter "the Guide").[1149] While supporting the value of animal research, the Guide acknowledges, "The decision to use animals in research requires critical thought, judgment, and analysis. Using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being."[1150] Two central principles governing the use of animals are *Replacement* and *Reduction*, which are defined by the Guide as follows:

> **Replacement** refers to methods that avoid using animals. The term includes absolute replacements (i.e., replacing animals with inanimate systems such as computer programs) as well as relative replacements (i.e., replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).
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> **Reduction** involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information. This approach relies on an analysis of experimental design, applications of newer technologies, the use of appropriate statistical methods, and control of environmentally related variability in animal housing and study areas.[1151]

Similar to animal research, human fetal tissue research is controversial, with the majority of American citizens opposing the sale of human fetal body parts for research.[1152] Moreover, it is widely acknowledged that the use of human embryos/fetuses for research purposes warrants

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[1148] Information about NDRI is available at: http://ndriresource.org/

[1149] National Research Council, Guide for the Care and Use of Laboratory Animals (2011), https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-use-of-laboratory-animals.pdf [hereinafter Guide].

[1150] *Id.* at 4.

[1151] *Id.* at 5.

[1152] A Rasmussen poll from 2015 indicates that 25% of likely voters support the sale of human fetal tissue, while 54% are opposed and 22% are undecided (Available: http://www.rasmussenreports.com/public_content/politics/current_events/abortion/voters_balk_at_sale_of_fetal_body_parts). A Fox News poll from 2015 indicates that voters are evenly split on the use of fetal tissue for research, with 48% approving of such research, and 47% disapproving (Available: http://www.foxnews.com/politics/2015/08/27/fox-news-poll-views-divided-over-issues-involving-abortion.html).

special consideration. For example, the 1994 NIH Report of the Human Embryo Research Panel produced under the Clinton administration states, "The Panel believes that because the preimplantation embryo possesses qualities requiring moral respect, research involving the ex utero preimplantation human embryo must be carefully regulated and consistently monitored."[1153] In light of the moral respect due to the human embryo/fetus, the decision to use human fetal tissue in research is also "a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human . . . well-being."[1154] Consequently, just as for animal research, the decision to use human fetal tissue "requires critical thought, judgment and analysis,"[1155] with the principles of *Replacement* and *Reduction* being applicable to all research programs using human fetal tissue.

Rigorous application of these principles would serve to limit the use of human fetal tissue to those proposals where this tissue is in fact required for the experimental question (*i.e.*, Class 1 proposals) and would reduce the overall use of such tissue to the minimum required for obtaining valid scientific results. Application of these principles would also serve as a vehicle for "critical thought, judgment and analysis" regarding what constitutes the most appropriate scientific model for a specific research question.

Recommendation 3: The NIH will establish guidelines for the use of human fetal tissue, modeled on the guidelines for animal research that include the principles of *Replacement* and *Reduction*. The NIH will mandate that these guidelines be applied to all grants proposing the use of human fetal tissue and that funding will be contingent on the investigator demonstrating that 1) human fetal tissue is required and appropriate for the proposed experiments, 2) there are no reasonable alternatives or replacements for the use of human fetal tissue, and 3) every effort has been made to reduce the amount of human fetal tissue employed in the proposed experiments.

Background for recommendation 4: Assuring continued availability of funding for research that requires human fetal tissue. The analysis of the House Select Investigative Panel indicates that, for a small number of research programs, human fetal tissue is the most appropriate scientific model (Class 1 grants). For a much larger number of research programs (Class 2 and Class 3), human fetal tissue is not the most appropriate model, and alternative models are available (Chapter 9.D.3). Application of the principles of *Replacement* and *Reduction* (See Recommendation 3, above) will serve to distinguish proposals that require human fetal tissue (Class 1) from proposals that do not. Appropriate classification of proposed research is required to assure continued funding for scientifically meritorious research that requires human fetal tissue.

Recommendation 4: The NIH will adopt a three-tiered classification system for proposals involving human fetal tissue as indicated below:

[1153] National Institutes of Health, Report of the Human Embryo Research Panel, vol. 1. 1994. Bethesda MD, https://repository.library.georgetown.edu/bitstream/handle/10822/559352/human_embryo_vol_1.pdf?sequence=1&isAllowed=y.

[1154] Guide at 5.

[1155] *Id.*

Class 1: Fetal tissue is required for the proposed study. There are no reasonable alternatives. These proposals will have met all of the requirements established by the NIH guidelines outlined in Recommendation 1 and will be fully eligible for funding, based on scientific merit and NIH funding priorities.

Class 2: Fetal tissue is not essential for the study. There are some scientific advantages to the use of fetal tissue, but alternatives exist. These proposals will have met some, but not all of the requirements established by the NIH guidelines outlined in Recommendation 1 and will be eligible for funding only under exceptional circumstances, as established by scientific merit and NIH funding priorities.

Class 3: Fetal tissue is not essential for the study. There are no scientific advantages to the use of fetal tissue, and alternatives exist. In some cases, postnatal tissue is more relevant to the scientific question. These proposals will have failed to meet the requirements established by the NIH guidelines outlined in Recommendation 1 and will be ineligible for NIH funding.

Background for recommendation 5: Federal funding for fetal tissue research. Human fetal tissue is necessary for a limited number of research programs (Class 1 grants). Currently, tissue for these projects is only available from elective termination of pregnancy. Should a program for obtaining cadaveric fetal tissue donation from preterm and stillborn infants prove effective (Recommendation 1), this would provide a consistent source of human fetal tissue that is both *scientifically* and *ethically* superior to tissue obtained from induced abortion. If this is the case, fetal tissue donation should be expanded, and public research dollars should be restricted to a source of tissue that better serves the interests of basic and clinical research while simultaneously being ethically acceptable to all American citizens.

Recommendation 5: The NIH will report to Congress on the use of parent-donated tissue from natural demise of preterm children, anticipated by Recommendation 1 above, and Congress shall appropriate funds for an expansion of this program and disallow grants funded by federal dollars to utilize human fetal tissue obtained from induced abortion.

BIOETHICS AND FETAL TISSUE

WEDNESDAY, MARCH 2, 2016

HOUSE OF REPRESENTATIVES,
SELECT INVESTIGATIVE PANEL,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The panel met, pursuant to call, at 10:00 a.m., in Room HVC–210, House Visitors Center, Hon. Marsha Blackburn (chairman of the panel) presiding.

Members present: Representatives Blackburn, Pitts, Black, Bucshon, Duffy, Harris, Hartzler, Love, Schakowsky, Nadler, DeGette, Speier, DelBene, and Watson Coleman.

Staff present: March Bell, Staff Director; Mike Bloomquist, Deputy Staff Director; Karen Christian, General Counsel; Rachel Collins, Investigative Counsel and Clerk; Andy Duberstein, Press Secretary; Chuck Flint, Counsel; Theresa Gambo, Human Resources and Office Administrator; Jay Gulshen, Staff Assistant; Mary Harned, Investigative Counsel; Peter Kielty, Deputy General Counsel; Graham Pittman, Legislative Clerk; Frank Scaturro, Special Counsel; Heidi Stirrup, Health Policy Coordinator; Matthew Tallmer, Investigator; Zachary Baron, Democratic Senior Counsel; Paul Bell; Democratic Communications Advisor; Jacquelyn Bolen, Democratic Professional Staff Member; Vanessa Cramer, Democratic Professional Staff Member; Matthew Henry, Democratic Fellow; Karen Lightfoot, Democratic Communications Director; and Heather Sawyer, Democratic Staff Director.

Mrs. BLACKBURN. The Select Investigative Panel will come to order, and the Chair recognizes herself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

I want to welcome all the witnesses who are here today, and I am going to introduce each of our witnesses in a moment. And I look forward to hearing the testimony from each of you on Bioethics and Fetal Tissue.

The last decade has produced tremendous change in medical research and therapies. We are in the middle of a Biotechnology Revolution. Certainly, in my home State of Tennessee, this is evident and even today we have members of BioTennessee who are on the Hill.

Each week an announcement from this industry presents a new therapy, or a new tool, or a new possibility in the search for life-saving cures for diseases and afflictions that cause untold pain and suffering. New words have entered our vocabulary: three-parent children, chimeras, CRISPR gene editing, and bioinformatics. Words like organ transplant or tissue rejuvenation seem like ancient history in favor of regenerative medicine, which might eventually reconstitute entire organs from adult stem cells. In a word, things are moving quite quickly.

Like all revolutions, ethical questions and moral challenges can lag behind, but the new information and knowledge in medical science raises important questions. What does it mean? What are the historic principles of "do no harm"? Promoting disinterested decisions by medical professionals and, very importantly, addressing the question of human dignity and personhood. Ours is not the first era to face such questions. The Nuremburg Code produced a human rights-based ethics statement after horrible information was revealed about experimenting on humans without permission. We learned, years after it was underway, about prisoners in China forced to donate organs or killed for their organs. We learned about the horrors of forced abortion and testing drugs on the poor and unaware after it had happened. We all remember the horrible reports about the syphilis studies on African Americans or forced sterilization of the mentally challenged years or even decades after it happened.

Last summer's videos revealed that something very troubling is going on related to fetal tissue and research. The weak, the vulnerable, those with no voice harvested and sold. There is something going on and something that deserves investigating, and it demands our best moral and ethical thinking.

This first hearing on ethics focuses our attention on procuring and transferring baby body parts and related matters. We will hear from professors who teach ethics, from medical practitioners, from those who do biomedical research, from those within America's faith traditions so that we as legislators might become informed about the ethical implications and issues for the woman who terminates a pregnancy, for the researcher, for the person who needs a cure, and for the baby.

This is then about bioethics. We did not invite our guests here to debate election-year politics, or journalism ethics, or whether this Select Panel should be funded. I ask my colleagues to join me in focusing on bioethics so that we might hear the best testimony our witnesses have to offer.

I welcome each and every one of you, and I look forward to hearing from you.

[The prepared statement of Mrs. Blackburn follows:]

PREPARED STATEMENT OF HON. MARSHA BLACKBURN

Welcome to all the witnesses who are here today. I will be introducing each of you in a moment and I look forward to hearing your testimony on Bioethics and Fetal Tissue.

The last decade has produced tremendous change in medical research and therapies. We are in the middle of a Biotechnology Revolution. Each week an announcement presents a new therapy or a new tool or a new possibility in the search for lifesaving cures for diseases and afflictions that cause untold pain and suffering.

New words have entered our vocabulary: three parent children, chimeras, CRISPR gene editing, and bioinformatics. Words like "organ transplant" and "tissue rejuvenation" seem like ancient history in favor of regenerative medicine, which might eventually reconstitute whole organs from adult stem cells. In a word, things are moving "fast".

Like all revolutions, ethical questions and moral challenges can lag behind. But the new information and knowledge in medical science-raises important questions: "What does it mean?" "What about the historic principles of 'Do no harm', 'Promoting disinterested decisions by medical professionals,'" and very importantly, "addressing the question of human dignity and personhood."

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Last summer's videos revealed that something very troubling that is going on related to fetal tissue and research. The weak, the vulnerable, those with no voice—harvested and sold—there is something going on, something that deserves investigating and that demands our best moral and ethical thinking.

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Welcome and I look forward to hearing from each of you.

Mrs. BLACKBURN. At this time, I yield 5 minutes to the ranking member, Ms. Schakowsky of Illinois.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Madam Chair. I want to make two key points. First, fetal tissue research has saved millions of lives and has the potential for saving millions more. That is why many Republicans have long supported and should continue to support the use of fetal tissue for research purposes.

Second, today's hearing is not part of a serious investigation into fetal tissue research or anything else. Twelve States, three congressional committees, and a grand jury in Texas have already investigated and found no evidence that Planned Parenthood is seeking to profit from the sale of fetal tissue. Indeed, the only criminal acts uncovered in the course of these investigations have been those of anti-abortion extremist David Daleiden, who is now under indictment in Texas for his role in manufacturing the deceptively edited videos that have fueled the Republicans' latest attacks on women and their doctors.

Faced with these facts, the Select Panel should have disbanded. Instead, the Chair has embarked on a partisan and dangerous witch hunt. Her actions are putting the privacy and safety of Americans at risk.

Over the repeated objection of the Democratic members of the panel, the Chair has sent dozens of document requests to academic institutions, medical schools, and healthcare providers across the country. She has already issued three unilateral subpoenas demanding the names of individual researchers, graduate students, medical students, doctors, and clinic personnel—and is threatening to issue more. There are no rules in place to protect these names from public disclosure. In fact, the Chair's staff has made it per-

fectly clear that any name turned over to the panel may be released to the public.

There is no reason to create such a database. And the Chair's abuse of her position as Chair to compel this information is, frankly, reminiscent of Senator Joe McCarthy's abusive tactics.

We live in a world where researchers who use fetal tissue are compared to Nazi war criminals and extremists have tried to burn clinics to the ground. We live in a world where women have to face a gauntlet of harassment to get health care and where there are threatening Web sites that identify reproductive healthcare providers, their families, and maps of the locations of their clinics and homes.

On the day after Thanksgiving, a gunman drove 60 miles to a Planned Parenthood clinic in Colorado Springs, killed three people, injured nine others, and terrorized doctors and patients. And when arrested, he uttered the words, "no more baby parts," a phrase that many of my Republican colleagues have invoked both before and after these murders and in connection with this panel's investigation.

Linking individuals' names to an investigation that the Republicans describe as examining the "harvesting" of "baby body parts" and the "horrific" practices of abortion providers puts people in danger. Our words and our actions matter.

The Chair has refused to explain why she needs a database of names. As the Washington Post Editorial Board asked just a few week ago, "How is the name of a graduate student who 5 years ago was an intern at a lab relevant to anything?" There is no apparent reason for this, other than harassment and intimidation. Republicans may not like the fact that abortion is legal and, therefore, safe for women in this country, but that is no excuse for putting students, researchers, women, and their doctors at risk.

The Democratic members of this committee have repeatedly asked the Chair to stop demanding this information. We have proposed reasonable rules that would prevent collection of certain information and otherwise protect the information that we do receive. So far, the Chair has ignored our requests. Nonetheless—I want to make this very clear to the entities that are under threat of subpoena or contempt from the Chair and to every researcher, doctor, and woman in America—Democrats will continue to fight to keep them safe.

The unfortunate truth is that this partisan pursuit of the manufactured false allegations of anti-abortion extremists is putting Americans in harm's way, and it must stop. It is time to turn our attention to ensuring, not attacking, critical medical research and women's access to health care.

With that, I request unanimous consent to enter into the record the February 21, 2016, Washington Post editorial, "The Planned Parenthood Witch Hunt." And I yield back the balance of my time.

[The information appears at the conclusion of the hearing.]

Mrs. BLACKBURN. And your entry is made, without objection. The gentlelady yields back her time.

Mr. NADLER. Madam Chairperson?

Mrs. BLACKBURN. The gentleman is recognized.

Mr. NADLER. I have a parliamentary inquiry, Madam Chair.

Mrs. BLACKBURN. Parliamentary inquiry. State your inquiry.

Mr. NADLER. Madam Chair, my colleague, the ranking member, noted in her opening remarks our concerns about your dangerous and sweeping demands for the names of individual researchers, graduate and medical students, doctors, and clinic personnel. Can you explain what rules govern these demands?

Mrs. BLACKBURN. The answer to your inquiry: We are entitled to the information and we are going to take the necessary——

Mr. NADLER. Under what rules are you entitled to the information, is my question.

Mrs. BLACKBURN. We are under the jurisdiction of the Rules of the House of Representatives and the Rules of the Committee on Energy and Commerce.

Mr. NADLER. Very well. Further parliamentary inquiry.

Mrs. BLACKBURN. The gentleman will state his inquiry.

Mr. NADLER. If we are under the Rules of the Committee on Energy and Commerce, Rule 16 of the Rules of the Energy and Commerce Committee requires that "The Chair shall notify the ranking minority member prior to issuing any subpoena under such authority. To the extent practicable, the Chair shall consult with the ranking minority member at least 72 hours in advance of a subpoena being issued under such authority. The chairman shall report to the members of the Committee on the issuance of a subpoena as soon as practicable but in no event later than one week after issuance of such subpoena."

Those rules require three things, Madam Chair: They require you to notify the ranking member in advance; they require you to consult with the ranking member and to do so 72 hours before issuing a subpoena; and they require you to report within a week to the committee.

On Friday, February 12th, you told Ranking Member Schakowsky during votes on the House floor that you would be issuing subpoenas the next week. We immediately asked for a meeting to discuss this and for a copy of the subpoenas so that we could see what we were requesting. Those requests were refused. You then issued the subpoenas on the 16th of February, 4 days after that conversation, and have yet to report on their issuance.

Madam Chair, can you explain what constitutes consultation and reporting within the meaning of Energy and Commerce Rule 16?

Mrs. BLACKBURN. Energy and Commerce Committee requires a conversation on the committee's plans, which I did. And I will remind the gentleman the resolution establishing this panel, House Resolution 461, stated that Rule 11 of the House of Representatives and the Rules of the Committee apply to this panel. Further, the Rules of the Committee on Energy and Commerce do not require subcommittees. And this panel, the functional equivalent of a subcommittee, are not required to first meet or organize before conducting business.

Mr. NADLER. Madam Chair, further parliamentary inquiry.

Mrs. BLACKBURN. State your inquiry.

Mr. NADLER. Whether what you have described is a long-standing practice, the fact is the ranking member made a direct request to discuss these particular subpoenas and have a copy of them. The flat refusal even to communicate with Democratic members has un-

fortunately been commonplace since the outset of this investigation and violates the duty under the rule to consult.

With regard to reporting, we have yet to receive any report on the issuance of these subpoenas, including—and this is critically important—exactly what information entities are refusing to produce and how that information is pertinent to this investigation.

Contrary to your public claims that these entities had not cooperated with the panel, they have in fact done so. They have turned over hundreds of document and to the extent there remains any disagreement, it appears to be over your demand that they turn over the names of students, researchers, doctors, and clinic personnel. To date, you have refused to explain how this information is pertinent to the investigation. The recipients of your demands are entitled to this information, as are your Democratic and Republican colleagues. It is incumbent on you, certainly prior to moving to issue or enforce a subpoena, to show how the information you demand is pertinent to the matters we are investigating.

Madam Chair, will you explain how the names of individual medical or graduate students, researchers, healthcare providers, and clinic personnel are pertinent to this investigation, please?

Mrs. BLACKBURN. No, sir, I am not going to do that. But I will let you know, Mr. Nadler, that copies of all the document requests have been made available to the minority. Copies of the subpoenas have been made available. And the requirements have been met.

And at this point, we are going to move on and introduce our first——

Mr. NADLER. No, Madam Chair, I have one further parliamentary inquiry, which I would——

Mrs. BLACKBURN. State your inquiry.

Mr. NADLER. I will state at the outset I disagree with the assertion that we need to compile a database of names to get answers that we can easily get from institutional representatives, persons who are akin to 30(b)(6) witnesses under the Federal Rules of Civil Procedure. You have refused to inform the subcommittee, to consult with the subcommittee. You should drop the demand for names and adopt the rules that we have proposed, which will ensure a more balanced and a fair investigation. If you will not change the rules, we should at least obey our current rules. We cannot proceed in flagrant violation of the rules, nor should we proceed with dangerous subpoenas that endanger the lives and physical safety of patients, providers, and researchers in a way that could make this committee complicit with any physical assaults on these people or any murders of these people.

I, therefore, move to quash the subpoenas.

Mr. PITTS. Madam Chair.

Mrs. BLACKBURN. The gentleman is recognized.

Mr. PITTS. I move to quash the motion.

Mrs. BLACKBURN. The gentleman from Pennsylvania moves to table the motion. The gentleman from Pennsylvania has moved to table the motion. The question occurs on approving the motion to table.

All those in favor of signifying to table the motion will say "aye."

All opposed say "no."

The "ayes" have it.

Ms. SCHAKOWSKY. Roll call vote requested.
Mr. NADLER. Roll call vote requested.
Mr. PITTS. Roll call.
Mrs. BLACKBURN. Roll call is requested.
The CLERK. Mr. Pitts.
Mr. PITTS. Aye.
The CLERK. Mr. Pitts, aye.
Mrs. Black.
Mrs. BLACK. Aye.
The CLERK. Mrs. Black, aye.
Mr. Bucshon.
Mr. BUCSHON. Aye.
The CLERK. Mr. Bucshon, aye.
Mr. Duffy.
Mr. DUFFY. Aye.
The CLERK. Mr. Duffy, aye.
Mr. Harris.
Mr. HARRIS. Aye.
The CLERK. Mr. Harris, aye.
Mrs. Hartzler.
Mrs. HARTZLER. Aye.
The CLERK. Mrs. Hartzler, aye.
Mrs. Love.
Mrs. LOVE. Aye.
The CLERK. Mrs. Love, aye.
Ms. Schakowsky.
Ms. SCHAKOWSKY. No.
The CLERK. Ms. Schakowsky, no.
Mr. Nadler.
Mr. NADLER. No.
The CLERK. Mr. Nadler, no.
Ms. DeGette.
Ms. DEGETTE. No.
The CLERK. Ms. DeGette, no.
Ms. Speier.
Ms. SPEIER. No.
The CLERK. Ms. Speier, no.
Ms. DelBene.
Ms. DELBENE. No.
The CLERK. Ms. DelBene, no.
Mrs. Watson Coleman.
Mrs. WATSON COLEMAN. No.
The CLERK. Mrs. Watson Coleman, no.
Mrs. Blackburn.
Mrs. BLACKBURN. Aye.
The CLERK. Mrs. Blackburn, aye.
Mrs. BLACKBURN. The clerk will report.
The CLERK. Mrs. Chairman, on that vote there were eight "ayes" and six "nays."
Mrs. BLACKBURN. The motion is tabled. At this time, we will introduce our first panel. I will ask that our panelists please move to the table as they are called forward.
First, Ms. Paige Comstock Cunningham. She is the Executive Director of the Center for Bioethics and Human Dignity. She is a fel-

low at the Institute for Biotechnology and the Human Future and a trustee of Taylor University.

Dr. Gerald Donovan. Dr. Gerald Kevin Donovan is Senior Clinical Scholar at the Kennedy Institute of Ethics at Georgetown University. He is also Director of the Pellegrino Center for Clinical Bioethics and Professor of Pediatrics at Georgetown.

Professor Alta Charo. Professor Charo is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison, where she is on the faculty of the law school and the Department of Medical History and Bioethics at the Medical School.

I want to welcome each of you. And at this point, I would like to make certain that as you are here, you are aware that the Selective Investigative Panel is holding an investigative hearing and will take testimony under oath.

Do you have an objection to testifying under oath?

Dr. DONOVAN. No.

Ms. CUNNINGHAM. No.

Ms. CHARO. No.

Mrs. BLACKBURN. The Chair then advises you that under the rules of the House Committee on Energy and Commerce, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today?

Dr. DONOVAN. No.

MMs. CUNNINGHAM. No.

Ms. CHARO. No.

Mrs. BLACKBURN. Thank you. If each of you will stand to be sworn in for your testimony.

[Witnesses sworn.]

Mrs. BLACKBURN. You are now under oath and subject to the penalties set forth in Title 18, Section 1001, of the U.S. Code. You may have 8 minutes to make a written summary—to provide a statement summary of your written testimony, and we thank each of you for providing that. I am going to ask that you make sure that your mike is on before you give your testimony and then that you will turn the mike off when you finish, and you will turn it back on when we move to the question portion.

And Dr. Donovan, we will begin with you for your testimony.

STATEMENTS OF G. KEVIN DONOVAN, M.D., DIRECTOR, PELLEGRINO CENTER FOR CLINICAL BIOETHICS, AND PROFESSOR OF PEDIATRICS, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE; PAIGE COMSTOCK CUNNINGHAM, EXECUTIVE DIRECTOR, CENTER FOR BIOETHICS AND HUMAN DIGNITY, TRINITY INTERNATIONAL UNIVERSITY; AND R. ALTA CHARO, WARREN P. KNOWLES PROFESSOR OF LAW AND BIOETHICS, UNIVERSITY OF WISCONSIN AT MADISON

STATEMENT OF G. KEVIN DONOVAN

Dr. DONOVAN. Well, thank you. Chairman Blackburn and members of the panel, I am pleased to have the opportunity to present testimony regarding the bioethical considerations in the harvesting, transfer, and use of fetal tissue and organs.

I am a physician trained in both pediatrics and clinical bioethics. I have spent my entire professional career caring for infants and children. It was this interest and concern that led me to further study in bioethics because I have always been concerned about the most vulnerable patients, those who need others to speak up for them, both at the beginning and at the end of life. I also have significant familiarity with research ethics, having spent 17 years as the chair of an IRB, although, I am, myself, not a research scientist. The IRB, as you know, is the board that monitors the rightness and the wrongness of medical research in order to protect human subjects. We took this aspect of our duties so seriously that I renamed our IRB the Institutional Research Ethics Board.

Four years ago I was called by my mentor, Dr. Edmund Pellegrino, to take his place as Director of the Center for Clinical Bioethics at Georgetown University. Our duties include ethics education for medical students and resident physicians, ethics consultation for patients and doctors at the hospital, as well as the promulgation of scholarly papers and public speaking. We focus on both clinical ethics, that which directly involves the good of patients, as well as addressing normative questions, those which involve right and wrong.

This is what we want young physicians to know: Medicine is a moral enterprise. Our actions have consequences that can be good or bad for patients, and we must always focus on the patient's good and avoid doing harm. So what does this mean for the topic at hand? We're talking about bioethics and the fetus. In order to make any moral judgments, we would have to be clear on the moral status of the fetus. Obviously, this is an area in which society has not reached a consensus, but that does not mean we cannot make sound judgments on the topic.

In a question of biomedical ethics, it is good to start with solid science. What do we know about the fetus with certainty? Well, first of all, we know that it is alive, that it represents growing, developing, cells, tissues, and organs, all of which develop increasing complexity and biologic sophistication, resulting in an intact organism, a human baby. Of course, this growth and development does not cease with the production of the baby, but continues for many years afterwards. As can be seen by this description, the fetus is not only alive, but is demonstrably human. I'm not talking about a potential human in the way that some parents talk about their teenagers as potential adults. I am referring to the scientific fact that a fetus constitutes a live human, typically 46XX or 46XY, fully and genetically human. In fact, it is the irrefutable humanness of these tissues and organs that has made them be of interest to researchers and scientists.

So, if a fetus is clearly both alive and human, can we justify taking these tissues and organs for scientific experimentation? If so, under what circumstances and what sort of consent or authorization should be required?

In the past century, medicine has made incredible progress resulting from scientific studies involving human tissues and organs, resulting in the development of medications, vaccines, and the entire field of transplantation medicine. Is there any difference between these accomplishments and those that would require the

harvesting of body parts and tissues from the fetus? First, we would have to admit that not all scientific experimentation has been praiseworthy. Studies done by Dr. Mengele in Germany and by American researchers in Guatemala and Tuskegee were morally abhorrent, and any knowledge gleaned from these would be severely tainted. No one would want to associate our current scientific studies involving the human fetus with such egregious breaches of research ethics. All that it takes to avoid such a comparison is a consensus on the moral status of the fetus.

Those who have proceeded with experimentation and research on embryonic and fetal cells, tissues, and organs typically have obtained them as the result of an abortion. It is this stark fact that makes such scientific endeavors controversial, because they have proceeded without the aforementioned consensus on the moral status of the fetus.

Because we know that the fetus is alive, and human, we must find some explanation for why it should not be treated with the same dignity that we accord all other human lives. The most frequent argument offered is that, although it is a human life, it is not a human person. Various criteria are offered for a definition of personhood, but none have been found universally acceptable. We, thus, have a standoff between those who would protect this early vulnerable human life and those that would deny that it deserves protection.

In order to resolve such an ethical dilemma, the guiding principle is this: One is morally permitted to take such a life once you can demonstrate with moral certainty that the life is not fully human. It is a concept that can be exemplified by the situation faced by a hunter when he sees a bush shaking. He may sincerely believe that it is a deer in the bush but if he kills it, prior to determining with certainty what it is that he is killing, he will be morally responsible, as well as legally, if he has in fact killed the farmer's cow, or worse yet, the farmer.

As we can see, two deeply held but opposing viewpoints need not be resolved unless someone intends to act upon them. Then, the one who intends to take the action resulting in the death of the disputed entity must not do so unless they can first show with moral certainty that their perception of its moral worth is irrefutable. Those who would not disturb the normal progression of its life bear no such burden.

It's my contention that such proof does not exist and deliberate fetal destruction for scientific purposes should not proceed until it does. Moreover, without disputing the arguable necessity of research on fetal tissues, an arguable necessity, I would also point out that harvesting it in such a way is unnecessary. Not only do cell lines already exist that were produced in such a fashion, but new cell lines could be obtained from fetal tissues harvested from spontaneous miscarriages. This is not a theoretical alternative. Georgetown University has a professor who has patented a method of isolating, processing, and cryopreserving fetal cells from second-semester, meaning 16-to-20-week-gestation, miscarriages. These have already been obtained and are stored in Georgetown freezers.

Moreover, the present practices of obtaining fetal tissues and organs would seem to go against the procedures that have been ap-

proved for others who harvest tissues and organs donated for transplantation. First, we follow a strict rule: the dead donor rule. It states that vital unpaired organs cannot be obtained unless the donor has died a natural death. This, obviously, is not the case in an induced abortion.

Moreover, such tissues or organs cannot be harvested without the consent of the patient or their proper surrogate. In pediatrics, parents are considered the normal proper surrogate. However, this interpretation rests on the presumption that the parent is acting in the best interests of the individual child. It is difficult to sustain such an interpretation when it is the same parent who has just consented to the abortive destruction of that individual fetus from whom those tissues and organs would be obtained.

Finally, we are at a difficult time in our Nation's history. We demonstrate much moral ambiguity in our approach to the human fetus. We have decided that we can legally abort the same fetus that might otherwise be a candidate for fetal surgery, even using the same indications as justification for acts that are diametrically opposed. We call it the fetus if it is to be aborted and its tissues and organs transferred to a scientific lab. We call it a baby, even at the same stage of gestation, when someone plans to keep it and bring it into their home.

Language has consequences, but it can also reflect our conflicts. We are a nation justly proud of the progress and achievements of our biomedical research, but lifesaving research cannot and should not require the destruction of life for it to go forward. If we cannot act with moral certainty regarding the appropriate respect and dignity of the fetus, we cannot morally justify its destruction. Alternatives clearly exist that are less controversial, and moral arguments exist that support our natural abhorrence at the trafficking of human fetal parts.

Surely we can, and surely we must, find a better way.

Thank you.

[The prepared statement of Dr. Donovan follows:]

Testimony of G.Kevin Donovan, M.D., MA

Director, Pellegrino Center for Clinical Bioethics

Professor, Department of Pediatrics

Georgetown University School of Medicine

Washington, DC

Hearing on

"Bioethics and Fetal Tissue"

Before the Select Investigative Panel

of the Committee On Energy and Commerce

US House of Representatives

March 2, 2016

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board that monitors the rightness and the wrongness of medical research in order to protect human subjects. We took this aspect of our duties so seriously that I renamed our IRB the *Institutional Research Ethics Board.* Four years ago I was called by my mentor, Dr. Edmund Pellegrino, to take his place as director of the Center for Clinical Bioethics at Georgetown University. Our duties include ethics education for medical students and resident physicians, ethics consultation for patients and doctors at the hospital, as well as the promulgation of scholarly papers and public speaking. We focus on both clinical ethics, that which directly involves the good of patients, as well as addressing normative questions, those which involve right and wrong actions.

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and the entire field of transplantation medicine. Is there any difference between these accomplishments and those that would require the harvesting of body parts and tissues from the fetus? First, we would have to admit that not all scientific experimentation has been praiseworthy. Studies done by Dr. Mengele in Germany, and by American researchers in Guatemala and Tuskegee, were morally abhorrent, and any knowledge gleaned from these would be severely tainted. No one would want to associate our current scientific studies involving the human fetus with such egregious breaches of research ethics. All that it takes to avoid such a comparison is a consensus on the moral status of the fetus.

Those who have proceeded with experimentation and research on embryonic and fetal cells, tissues, and organs typically have obtained them as the result of an abortion. It is this stark fact that makes such scientific endeavors controversial, because they have proceeded without the aforementioned consensus on the moral status of the fetus. Because we know that the fetus is alive, and human, we must find some explanation for why it should not be treated with the same dignity that we accord all other human lives. The most frequent argument offered is that, although it is a human life, it is not a human *person.* Various criteria are offered for a definition of personhood, but none have been found universally acceptable. We thus have a standoff between those who would protect this early vulnerable human life and those that would deny that it deserves protection. In order to resolve such an ethical dilemma, the guiding principle is this: one is morally permitted to take such a life once you can demonstrate with moral certainty that the life is not human. It is a concept that can be exemplified by the situation faced by a hunter when he sees a bush shaking. He may sincerely believe that it is a deer in the bush, but if he kills it prior to determining with certainty what it is that he is killing, he will be morally responsible (as well as legally) if he has in fact killed the farmer's cow, or worse yet, the farmer. As we can see, two deeply held, but opposing viewpoints need not be resolved unless someone intends to act upon them. Then, the one who intends to take the action resulting in the death of the disputed entity must not do so unless they can first show with moral certainty that their perception of its moral worth is irrefutable. Those who would not disturb the normal progression of its life bear no such burden. It's my contention that such proof does not exist, and deliberate fetal destruction for scientific purposes should not proceed until it does.

Moreover, without disputing the arguable necessity of research on fetal tissue, I would also point out that harvesting it in such a way is unnecessary. Not only do cell lines already exist that were produced in such a fashion, but new cell lines could be obtained from fetal tissues harvested from spontaneous miscarriages. This is not a theoretical alternative. Georgetown University has a professor who has patented a method of isolating, processing, and cryopreserving fetal cells from second trimester (16 – 20 week gestation) miscarriages. These have already been obtained and are stored in Georgetown freezers.

Moreover, the present practices of obtaining fetal tissues and organs would seem to go against the procedures that have been approved for others who harvest tissues and organs donated for transplantation. First, we follow a strict rule, the dead donor rule. It states that vital unpaired organs cannot be obtained unless the donor has died a natural death. This obviously is not the case in an induced abortion. Moreover, such tissues or organs cannot be harvested without consent of the patient or their proper surrogate. In pediatrics, parents are considered the normal proper surrogate. However, this interpretation rests on the presumption that the parent is acting in the best interests of the individual. It is difficult to sustain such an interpretation when it is the same parent who has just consented to the abortive destruction of the individual from whom those tissues and organs would be obtained.

We are at a difficult time in our nation's history. We demonstrate much moral ambiguity in our approach to the human fetus. We have decided that we can legally abort the same fetus that might otherwise be a candidate for fetal surgery, even using the same indications as justification for acts that are diametrically opposed. We call it the fetus if it is to be aborted and its tissues and organs transferred to a scientific lab. We call it a baby, even at the same stage of gestation, when someone plans to keep it and bring it into their home. Language has consequences, but it can also reflect our conflicts. We are a nation justly proud of the progress and achievements of our biomedical research, but lifesaving research cannot and should not require the destruction of life for it to go forward. If we cannot act with moral certainty regarding the appropriate respect and dignity of the fetus, we cannot morally justify its destruction. Alternatives clearly exist that are less

controversial, and moral arguments exist that support our natural abhorrence at the trafficking of human fetal parts. Surely we can, and surely we must, find a better way.

Mrs. BLACKBURN. Thank you.
Ms. Cunningham, you are recognized.

STATEMENT OF PAIGE COMSTOCK CUNNINGHAM

Ms. CUNNINGHAM. Madam Chair Blackburn, Ranking Member Schakowsky, and members of the Select Investigative Panel, thank you for the opportunity to speak about the ethics surrounding the use of fetal tissue for research.

My argument, which is expanded in my written testimony, is three-fold. First, respect the fetus. The fetus is a human being, who is entitled to the protections of modern guidelines for medical research. The foundational principles of respect for persons should apply to unborn children without distinction.

Second, you cannot take a life and then give away the body. Participants in elective abortion, including the mother, are morally disqualified from consenting to donating the body, organs, or tissue of the now-dead fetus for research purposes.

And third, there are better, more ethical options.

First, at the core of our concern is the fundamentally important question: Who or what is the fetus? The biological facts are clear. The fetus is an organism in charge of her own integral organic functioning, enduring and developing over time, through all the stages of human existence. First, embryo, fetus, infant, adolescent, and adult. Rather than being a distinct and lesser form of human life, the fetus is a distinct human being at a particular stage of development. She is not a potential human being but an actual human being. No one has the right to take her life by force.

Those who are responsible for her death have failed to recognize the fundamental principle of human dignity. They have no moral claim to donate or assign her body, organs, or tissues to others. Even more, others should not profit from this wrongful act, whether for monetary gain, scientific reputation, better health, or even to claim, "These cures are so wonderful, how could anyone oppose this research?"

The regulatory scheme of protection for human subjects of medical research has continued to expand protection for research subjects to ensure that their participation is voluntary and fully informed and that the research is for their benefit, or if not, causes no more than minimal harm and that they may have access to the benefits of the research. Protections have been explicitly extended to most vulnerable populations but not to the fetus to be aborted. If she were being treated in utero for her own benefit, the HHS Policy for Protection of Human Subjects provides heightened protection for her well-being. That same HHS policy also provides special protections for prisoners but not for the fetus to be aborted.

Some have argued that we all share a moral obligation to contribute our organs or bodies after death for the good of society. Others claim the principle of proximity, the view that we would want to help those most like us. In her analysis of fetal tissue transplantation, Kathleen Nolan elaborates on a problem with this view, and I quote: "In the setting of elective abortion a cruel irony thus emerges: fetuses that have been excluded from membership in the human community by a societally sanctioned maternal decision to

abort now have obligations to that same community because of membership in it." We reject this cruel irony.

Now, Federal law does attempt to erect a barrier of sorts between the decision to abort and the decision to donate. For example, the procedure must not be altered in any way to accommodate researchers' needs. And elements of informed consent for tissue donations should include telling the donor's family if the tissue will be used outside the U.S.; whether it will be modified into a commercial product; the distinction between the for-profit and nonprofit entities involved; and that she be given a copy of the form she signed.

Is the woman contemplating donation made aware of the specific body parts that will be harvested? The request may be for the unborn child's eyes, his brain, his kidneys that might be transplanted into a rat, his thymus, or pancreas. But the greatest demand might be for his liver. Women might find this factual information relevant to their decision.

So, how is effective informed consent accomplished in the setting where there is no established institutional oversight to ensure compliance with this regulation, as the vast majority of abortions take place in clinics that are outside the ordinary system of health care and the accreditation requirements that exist in hospitals and ambulatory surgical centers? Further, abortion clinic owners vigorously resist health standards that are imposed on all other ambulatory surgical centers.

The history of the use of human bodies and parts in medical education and research reveals a disturbing pattern of first seeking access from the most disadvantaged in society. One national commission noted that there have been "instances of abuse in the area of fetal research and that the poor and minority groups may bear an inequitable burden as research subjects." It would be enlightening to know whether that abuse continues and the demographic profiles of women who are solicited to donate.

There is yet another reason to oppose the current practices of fetal tissue research: It is unnecessary. Alternative, ethically derived sources of cells exist and they are working. My written testimony addresses this more fully, and I will defer to other witnesses to speak to this more directly.

A just society has no moral or other claim on electively aborted fetal bodies, organs, or tissues. Unborn children scheduled for termination by induced abortion are among, if not the most vulnerable, members of the human family. As has been said by many leaders in many ways, a society will be judged by how we treat our weakest, most vulnerable members.

Curbing the current practices of fetal tissue research would be a small but very significant step toward honoring the dignity of all our members.

Thank you.

[The prepared statement of Ms. Cunningham follows:]

TESTIMONY OF PAIGE COMSTOCK CUNNINGHAM, JD,

EXECUTIVE DIRECTOR, THE CENTER FOR BIOETHICS & HUMAN DIGNITY

TRINITY INTERNATIONAL UNIVERSITY

DEERFIELD, ILLINOIS

HEARING ON

"BIOETHICS AND FETAL TISSUE"

BEFORE THE SELECT INVESTIGATIVE PANEL

OF THE COMMITTEE ON ENERGY AND COMMERCE

U. S. HOUSE OF REPRESENTATIVES

MARCH 2, 2016

Chairman Blackburn and members of the Panel, thank you for inviting me to present my views, which are consistent with those of my employer The Center for Bioethics & Human Dignity on the bioethical issues involving the use of fetal tissue for research and therapeutic purposes.

The Center is a Christian bioethics research center at Trinity International University in Deerfield, Illinois. Founded more than twenty years ago, the Center's mission is to ensure that academic and clinical discussions on bioethics include a robust understanding of human dignity within the broad Judeo-Christian Hippocratic traditions. By so doing, we endeavor to help others make sound ethical choices when faced with concerns that arise at the intersection of medicine, science, and technology.

As a lawyer who has turned her professional attention to bioethics, I am deeply concerned with the ethical issues surrounding the procurement and use of fetal bodies, organs, and tissues in research.

There should be no doubt that the use of cadaveric fetal organs and tissue for research and clinical applications raises serious moral and ethical concerns, concerns that are heightened when the organs and tissue are obtained as the result of elective abortion. A vast literature proves this fundamental point, as does a simple statement on the website of the Office of Intramural Research, National Institutes of Health: "Research using fetal tissues is not prohibited but is highly regulated."[1] Were there no controversy, the literature would not be vast, and the regulation would be light.

The fetus is a human subject entitled to the protections that both traditional and modern codes of medical ethics provide to human subjects. The fetus, as a uniquely vulnerable and dependent human person, merits the same (or even heightened) protections that modern declarations and codes of medical ethics impose on all human subject research. Current legal standards and other guidelines fail in this regard, giving insufficient recognition to the moral status of the fetus and violating norms of informed consent.

Biological and moral status of the fetus. (What follows is the briefest mention of serious philosophical arguments about the moral status of the fetus that have been addressed extensively elsewhere.) The human fetus, and in its earlier stages, the embryo, has been variously viewed as "a nonpersonal organism;"[2] tissue;[3] a potential or future person;[4] a human entity entitled to

[1] https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/fetal-tissue-research.

[2] Joseph Fletcher, in *the National Commission for the Protection of Human Subject of Biomedical and Behavioral Research.* Research on the Fetus: Report and Recommendations. July 25, 1975. p. 32

special respect or special regard;[5] a human being whose moral standing increases during gestation;[6] or an immature human being with the same moral status as an adult human being.[7]

Science establishes that the nascent human, as a blastocyst, then an embryo, then a fetus, is a organism of the species *Homo sapiens*, and genetically distinct from both father and mother. She[8] is a determinate humane being, enduring over time, who directs his own integral organic functioning. Given time, nutrition, and a safe environment, the embryo, then fetus, will grow and develop through all the natural stages of human life.[9] Rather than being a distinct—and lesser—form of human life, the fetus is a distinct human being at a particular developmental stage. As such, she is not a potential human being, but an actual human being, whose life should not be intentionally ended by force. It is "morally impermissible to engage in any research, for any purpose, that involves the destruction of human beings at any stage of their lives, including the embryonic stage, or in any condition, however weak or dependent."[10] Those who are responsible for terminating the life of a fetus have failed to recognize this fundamental principle of human dignity, and thus have no moral claim to be able to donate or assign the body, organs, or tissues of the fetus to others, regardless of the nobility of purpose.

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[3] Richard Wasserman, in Research on the Fetus: Report and Recommendations. 39.
[4] Alberto Giubilini and Francesca Minerva, "After-birth abortion: why should the baby live?" *J Med Ethics.* 39:5 (May 2013):261-263.
[5] *Davis v. Davis,* 842 S.W.2d 588 (Tenn. 1992).
[6] C. Strong, "The Moral Status of Preembryos, Embryos, Fetuses, and Infants." J Med Philos. 1997 Oct;22(5):457-78.
[7] Robert George and Christopher Tollefsen, *Embryo: A Defense of Human Life.*(New York: Doubleday, 2008).
[8] The fetus may be variously referred to as 'it,' 'him,' 'her,' or 'him/her.' None should be interpreted to diminish the full humanity and moral status of the fetus.
[9] Maureen Condic, "Human Embryology: Science Politics versus Science Facts," *Quaestiones Disputatae,* vol. 5 no. 2, (Spring 2015):47-60.
[10] George and Tollefsen, 25.

Legal status of the fetus. The legal status of the embryo and fetus is at odds with the scientific facts and moral reality. In *Roe v. Wade,* The U.S. Supreme Court decided that the fetus is not a "person" for purposes of constitutional rights.[11] Elective abortion, the source of most fetal tissue used in research, has been permitted throughout pregnancy since 1973. Lamentably, the US is one of only four nations that permit abortions after viability.[12] Unlike born human beings, the fetus-to-be-aborted lacks meaningful constitutional, statutory, or regulatory protection. This exposure makes the fetus vulnerable to callous disregard for her well-being, and makes it easier to regard her as the "other," as an object of interest to researchers, rather than as a human being with interests of her own. Human fetal tissue procurement entities facilitate acquisition of cadaveric fetal organs and tissue, but this does not, in itself, insulate researchers from the moral concerns. Yet, the history of medical research ethics is one of increasingly rigorous protections, particularly for vulnerable populations, such as children as those who may not benefit directly from the research. The fetus-to-be-aborted would seem to be among the most vulnerable human beings of all, yet due to the mother's elective abortion, is beyond the reach of most regulatory consideration.

Human subject research ethics. If the fetus is a human being, then he or she should be entitled to legal and ethical protections for human subject research. Contemporary ethical guidelines for using human subjects in medical research generally adhere to the principles of respect for persons or autonomy, beneficence, nonmaleficence, and justice. Beginning with the Nuremberg Code of 1947 and its condemnation of research on unwilling subjects, principles of medical research have expanded protections for children and other vulnerable populations,

[11] 410 U.S. 113 (1973).

[12] The other three nations are Canada, China, and North Korea. "United States Abortion Policy in the International Context." Americans United for Life. Available at http://www.aul.org/united-states-abortion-policy-in-the-international-context/.

ensured that consent is genuinely informed and voluntary, required that risks to participants be minimized, and expanded access for participants to the benefits of the research. The World Medical Association's Declaration of Helsinki in 1962 laid down the cornerstone principles for physicians and other participants in medical research involving human subjects. Two of its provisions included separating the roles of physician and investigator, and distinguishing therapeutic research from that which was "purely scientific and without therapeutic value to the person subjected to the research."[13] Further, the Declaration applies not only to human subjects, but also to research on "*identifiable human material* or identifiable data."[14] In fact, international studies using fetal cadaveric tissue report compliance with the Declaration of Helsinki in the procurement and processing of tissue or organs. Even companies that do not conduct trials or studies *in vivo* follow the principles of the Declaration.[15]

A few years after the Declaration of Helsinki was adopted, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1975 addressed research involving living, nonviable fetuses. Although much of the report focused on the to-be-aborted fetus, a majority of the members also approved the use of the dead fetus, fetal tissue and fetal material.[16] The use of fetal tissue was more directly addressed in 1998 by the NIH Human Fetal Tissue Research Transplantation Panel. New guidelines had to be developed for research using cadaveric fetal organs and tissue. The NIH panel attempted to erect a barrier between abortion and fetal tissue research, to keep the contested morality of abortion from tainting the ethics of using aborted fetal remains. The Committee for Pro-Life Activities of the National Conference of Catholic Bishops contended that even if *in principle* there could be an ethical use

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[13] Declaration of Helsinki, 1964, Introduction.
[14] Declaration of Helsinki, 2000, para. 1.
[15] See, e.g., Genoskin, http://www.genoskin.com/en/declaration-of-helsinki/,
[16] Research on the Fetus, 75.

of abortion-derived fetal tissue, it was difficult to see how the *practice* could avoid "a morally unacceptable collaboration with the abortion industry."[17] Current events suggest that the problem has not been resolved, and that morally unacceptable collaboration continues.

Federal law permits and regulates transplantation of fetal tissue from induced abortion, as well as spontaneous abortion and stillbirth.[18] Although originally drafted in response to fetal tissue transplantation experiments, §289g-1 of Title 8 of the Code of Federal Regulations is interpreted to apply to the use human fetal tissue in research.[19] Fetal tissue research is also subject to the Common Rule, which requires that an Institutional Review Board (IRB) approve the research protocol.[20] The woman's participation must be solicited separately from, and subsequent to, her decision to abort. Further, there must be "no alteration of the timing, method, or procedure used to terminate the pregnancy solely for the purposes of obtaining the tissue."[21] Whether any alteration was in fact made is not independently verified; the physician merely has to sign a statement to that effect. There is no effective oversight to ensure compliance with this regulation, as the vast majority of abortions take place in clinics that are outside the ordinary system of healthcare, and thus are not subject to established institutional oversight and accreditation requirements that exist in hospitals and ambulatory surgical centers. Further, they rigorously resist health standards that are imposed on other ambulatory surgical centers from being applies to their abortion clinics.

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[17] NIH Human Fetal Tissue Transplantation Research Panel. Report of the HFTTR Panel. 1988. II:E14.
[18] 42 U.S.C. §289g-1 and §289g-2
[19] Kristin Finklea et al., "Fetal Tissue Research: Frequently Asked Questions." *Congressional Research Service.* July 31, 2015. Available at https://www.fas.org/sgp/crs/misc/R44129.pdf.
[20] "The Common Rule is the informal name given to core federal regulations governing the protection of human subjects in research supported or conducted by the federal government." *Ibid.*, 8, fn. 33.
[21] 42 U.S.C. sec, 289g-1(2)(A)(ii).

More recent guidelines for federally funded research exhibit solicitude for living fetuses as research subjects, but not for cadaveric fetuses.[22] If the research involves a fetus-to-be-born, both mother and father must consent. But if the mother chooses to terminate her pregnancy, only her consent is required for research using the fetal remains. To insulate fetal tissue donation from encouraging abortion, the woman must not be offered monetary or other inducement to terminate her pregnancy.[23] Again, this takes place outside of established institutional oversight.

Two provisions of the most recent revision of the Declaration of Helsinki in 2000 are worth noting. First is the revision's statement that "considerations related to the well-being of the human subject should take preference over the interests of science and society."[24] Although the dead fetus is not a "human subject," it does seem that the interests of "science and society" have outweighed concern for the fetus whose death is not due to accident or disease, but due to her vulnerable status of being undesired by her mother. Second, the Declaration rejects using people as a means to an end, particularly vulnerable populations, that is, "those who will not benefit personally from the research."[25] Of course, even if the research could benefit *other* fetuses in utero, this would still be a case of using this fetus as a means to that end.

For the most part, the trajectory of the development of public policy on protection of human subjects in medical research is one of continual expansion, and heightened concern to ensure that vulnerable populations are not disadvantaged or exploited. This circle of concern ought to include the fetus-to-be-aborted. Consequently, the only permissible research involving

[22] 45 C.F.R. §46.204.
[23] 45 C.F.R. §46.204(h).
[24] Declaration of Helsinki, para. 5.
[25] Declaration of Helsinki.

human fetuses ought to be research that is for their benefit, or if not for their benefit, research that causes no more than minimal harm.[26]

Thus far, my comments have focused on the general principles of research ethics that ought to be applied to research involving fetal tissue obtained as the result of elective abortion. I now turn to the specific issue of informed consent, a prerequisite for ethical research on human subjects. In this specific context, the ethics of consent cannot be limited to the standard criteria of competence, capacity, understanding, and ability to communicate. In addition, we must consider the moral agency of the person called upon to give consent, that is, the mother of the fetus-to-be-aborted. Our assessment of her moral agency will in turn depend on our position regarding the status of the unborn child, and the ethics of abortion.

If one takes the perspective that the fetus possesses diminished moral interests, or none at all, her decision to abort is not problematic. Thus, the mother might choose to consent for the sake of "advancing research" or "eradicating a disease." Or, she might project what her unborn child would have wanted. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral researched discussed the "principle of proximity," the view that we would want to help those most like us. Thus, where therapies or research are being developed to help pregnant women, fetuses, and premature neonates, the fetus might be viewed as a subject who would "want" to help those proximate others.

Some ethicists would go further and argue that each of us has an obligation to provide our our own body to the human community upon our death, and, by extension, impute this obligation to the fetus. Thus, the mother would be "consenting" on behalf of her fetus, fulfilling an imputed

[26] This might include research such as observational studies and nonintrusive measurement.

fetal obligation to the community he is not permitted to enter. In her analysis of fetal tissue transplantation, Kathleen Nolan elaborates on a problem with this view:

> In the setting of elective abortion a cruel irony thus emerges: fetuses that have been excluded from membership in the human community by a societally sanctioned maternal decision to abort now have obligations to that same community because of membership in it.[27]

We reject this "cruel irony." The fetus's "obligation" to the human community does not warrant overriding the principles of protection and informed consent.

A similar perspective is expressed in the advocacy of universal organ conscription, based on the principle that "dead bodies are a public resource that may be deployed to serving the common goal of saving human life."[28] The U.S. has not adopted a moral theory of organ donation based upon "obligation to the community" or "public resource." Neither have we adopted the rule of "presumed" or "mandatory" consent. Instead, we have preserved the long-standing rule of prospective actual consent.

In consenting to terminate her pregnancy by abortion, the mother compromises her moral agency to also consent to the use of the fetal remains by others. Even though she is not the primary actor in the death of her unborn child, her consent is necessary to others carrying out the procedure.[29] By virtue of her choice to end her child's life, she is morally disqualified from "donating" that child's remains. So, too, are the other participants in the abortion procedure.

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[27] Kathleen Nolan, "*Genu gist Genug:* A Fetus Is Not a Kidney," *Hastings Center Report,* 18:6 December (1988): 13-19

[28] Nolan, 14.

[29] See, e.g., Robert D. Orr, "Addressing Issues of Moral Complicity: When? Where? Why? And Other Questions." The Center for Bioethics & Human Dignity. Available at: https://cbhd.org/content/addressing-issues-moral-complicity-when-where-why-and-other-questions.

Thus, we are left with no one morally qualified to consent, an ethical barrier not reflected in the current regulatory framework, a framework that unreflectively presumes full moral agency on the part of the mother and the abortion provider.

Even if it were morally permissible for a woman seeking abortion to donate fetal remains for research, we question whether the process for obtaining such consent meets current norms for obtaining informed consent. To illustrate this concern, I will now examine key principles of informed consent that are placed at risk or violated outright by current procedures for obtaining consent to fetal tissue donation.

Process. As stated by the Department of Health and Human Services, "informed consent is a process, not just a form."[30] Thus, valid consent is more than a point in time, or a signature on a document. Procedures should be "designed to educate the subject population in terms that they can understand."[31] An informed consent process takes time, and time represents a business cost/expense, and optimally involves someone who accompanies the patient.

Patient perspective. As someone who has sat in on informed consent discussions with a physician, either as a family member or for myself, I have experienced the well-known phenomenon of a competent patient not remembering details of what was discussed. Had I not been present, taking notes, and asking questions, much of the conversation would have been lost. Where surgery was contemplated, the informed consent discussion took place twice, the second time just before the procedure. The stress of surgery may make it difficult to process the long-term implications of an immediate decision, let alone future regrets or satisfaction. Contemplating an abortion is a stressful event. As the UK Human Tissue Authority (HTA) writes

[30] "Informed Consent Tips (1993)," Office for Protection from Research Risks, Department of Health and Human Services. http://www.hhs.gov/ohrp/policy/ictips.html.
[31] Ibid.

that, "the loss or termination of a pregnancy, whatever the circumstances, is clearly an exceptionally sensitive and emotional time for a woman."[32] The HTA further notes that even if she does decide how to dispose of "pregnancy remains," she "may change her mind at a later date or ask about what arrangements were made."[33]

Whether the mother's decision to consent to the use of her fetus's body, organs, or tissue for research can be truly informed is problematic. Federal law requires that she must consent to the abortion prior to being solicited to consent to research using the aborted fetal tissue.[34] How is the solicitation to donate tissue insulated from her abortion decision? Does it occur moments before the surgery? It would be relevant to know the timing of the solicitation, who is talking to the patient, and the nature of the discussion. Is the woman given a copy of the informed consent form(s) she signs? Do they contain detailed information about the kind of research being conducted, potential benefits expected from the research,[35] and how the identity and origin of the tissue will be disclosed or protected?[36] Is she made aware of the specific body parts that will be harvested? The request may be for the unborn child's eyes,[37] her brain,[38] her kidneys that might be transplanted into a rat,[39] her thymus, or pancreas.[40] But the greatest demand might be for her liver.[41] Women might find this factual information relevant to their decision.

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[32] "Guidance on the disposal of pregnancy remains following pregnancy loss or termination" (March 2015). Human Tissue Authority, 3. https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf

[33] "Guidance on the Disposal of Pregnancy Remains," 3-4.

[34] 42 U.S.C. sec. 289g-1(b).

[35] 45 CFR Subtitle A sec. 46.116(a)(3).

[36] See, e.g., "Informed Consent Tips (1993)," Department of Health and Human Services, Office for Protection from Research Risks. "The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence."

[37] http://www.baltimoresun.com/health/bs-hs-fetal-tissue-20150815-story.html

[38] http://www.scientificamerican.com/article/the-truth-about-fetal-tissue-research/

[39] http://www.medicaldaily.com/kidney-harvested-aborted-human-fetus-grown-rat-end-organ-donor-shortage-scientists-319186.

Current practices involving adults justify raising these concerns. A comprehensive study by Siminoff and Traino in 2013, of over 1,000 cases of adult tissue donation noted that specific elements of informed consent were often missing, such as how the tissue will be stored; notification if the tissue is deemed unusable; whether the tissue will be used outside the US; whether the tissue will be modified (e.g., into commercial products such as penile enlargements, or reconstructive surgeries such as eyelid repair); family receipt of a copy of the informed consent document; and, the morally relevant distinctions between the 'for profit' and 'nonprofit' organizations involved.[42] Siminoff and Traino's findings are echoed by the conclusions of the HHS Office of Inspector General's report that "Tissue banking and processing practices have gradually diverged from donor families' expectations in recent years."[43] In fact, donors may think that their loved one's body will be used for immediately life-saving procedures or for medical education, only to learn to their horror and dismay, that all "usable" body parts were harvested,[44] or that the body was used as a crash test dummy.[45] One study revealed that 73% of

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[40] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4172669/

[41] See Rossella Semeraro,[1,*] Vincenzo Cardinale,[1,*] Guido Carpino,[2,3] Raffaele Gentile,[1] Cristina Napoli,[1] Rosanna Venere,[1] Manuela Gatto,[1] Roberto Brunelli,[4] Eugenio Gaudio,[2] and Domenico Alvaro[1,4] "The fetal liver as cell source for the regenerative medicine of liver and pancreas," Ann Transl Med. 2013 Jul; 1(2): 13. The authors note that "fetal liver is becoming the most promising and available source of cells" and is "highly available." http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4200630/.

[42] Laura A. Siminoff and Heather M. Traino, "Consenting to Donation: An Examination of Current Practice in Informed Consent for tissue Donation in the US." *Cell Tissue Bank* 14(1) (March 2013): 85-95

[43] "Informed Consent in Tissue Donation: Expectations and Realities." Office of Inspector General, Department of Health and Human Services. (January 2001), iii.

[44] See, e.g., Kate Wilson, Vlad Lavrov, Martine Keller, Thomas Maier, and Gerard Ryle, "Skin, Bones and Tissue for Sale: How the Dead Are Being Used for Grisly Trade in Human Body Parts." *Daily Mail,* July 17, 2012. http://www.dailymail.co.uk/news/article-2175006/Skin-bones-tissue-sale-How-dead-used-grisly-trade-human-body-parts.html.

[45] Mark Katches, William Heisel, Ronald Campbell, "Body Donors Fueling a Booming Business," *Orange County Register*, April 17, 2000. Available online at http://www.sweetliberty.org/issues/hate/bodybrokers.htm.

families were not aware that the body tissue of their loved one would be bought and sold, and they found the practice unacceptable.

Privacy. Concerns about privacy are not limited to disclosure of identifiable information (which raises the question: who is the subject here? Does "identifiable information" apply on to the fetus, or does it extend to the mother as well? As they are genetically distinct human beings, her DNA would not be involved, unless placental and umbilical tissues were harvested.). There may be additional concerns about how the woman is selected for solicitation. Who has access to her medical records, and are they authorized by law to do so?

Discrimination. In the history of the use of human bodies and tissues for medical education and research, there is a disturbing pattern of first seeking access to the bodies and organs of the most disadvantaged in society. The 1975 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research noted that there had been "instances of abuse in the area of fetal research" and "that the poor and minority groups may bear an inequitable burden as research subjects."[46] It would be important to know the demographic profiles of women who are solicited to donate. Is there a disproportionate representation from poor or educationally disadvantaged women? From minority groups? In her discussion of the use of fetal tissue for transplantation, Nolan notes that if we make the move toward "routine salvage," this could signal a move toward the same treatment of adult cadavers "as a basic mode of cadaveric treatment," demonstrating the "harsh but fairly consistent historical practice of looking first to society's outcasts when new necrogenous materials (such as autopsy specimens) are needed."[47] Further, the informed consent process itself may be discriminatory. The first

[46] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Research on the Fetus: Report and Recommendations, July 25, 1975, 62.
[47] Nolan, p. 15.

comprehensive study in the U.S. on consenting to tissue donation noted that older adults and nonwhites (African Americans, Asians, and Hispanics/Latinos) were given less information that younger, white decision makers.[48]

If such ethical problems exist in research involving adult cadaveric tissue, where institutional oversight is presumably rigorous, how much more reason do we have to think that they exist in the less-regulated context of free-standing abortion clinics?

There is yet another reason to oppose the current practices of fetal tissue research: it is unnecessary. While fetal tissue research has been going on for decades, its results have been meager.[49] There are three general areas of application: fetal tissue transplantation, vaccine development, and basic biological research. Fetal tissue transplantation has had few successes, and a number of lamentable, even "devastating" results.[50] Although early vaccine lines, most notable poliovirus, were developed from tissue harvested from aborted fetuses, "newer cell lines and better culture technique make this reliance on fetal cells an antiquated science."[51] The CDC and medical experts have agreed that no new fetal tissue is needed to develop rubella and other vaccines that grow in human cell culture.[52] Basic research also "relies on antiquated science and

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[48] Laura A. Siminoff and Heather M. Traino, "Consenting to Donation: An Examination of Current Practice in Informed Consent for tissue Donation in the US." *Cell Tissue Bank* 14(1) (March 2013): 85-95.

[49] See summary and references at David A. Prentice. Written testimony: Wisconsin Assembly Committee on Criminal Justice and Public Safety. August 11, 2015. Available at https://lozierinstitute.org/written-testimony-of-david-a-prentice-ph-d-in-support-of-wisconsin-bill-to-prohibit-sales-and-use-of-fetal-body-parts-from-abortion/.

[50] Gina Kolata, "Parkinson's Research Is Set Back by Failure of Fetal Cell Implants," *New York Times,* March 8, 2001. Available at http://www.nytimes.com/2001/03/08/us/parkinson-s-research-is-set-back-by-failure-of-fetal-cell-implants.html?pagewanted=all.

[51] Prentice, Written Testimony: Wisconsin Assembly Committee on Criminal Justice and Public Safety.

[52] https://www.facebook.com/vaccinationinformationnetwork/posts/144838112258 See also http://hsionline.com/2015/09/30/vaccines-2/

cell cultures."[53] More progressive alternatives include induced pluripotent stem (iPS), an unlimited, ethically-derived source of cells, "which can be produced from tissue of any human being, without harm to the individual donor, and with the ability to form virtually any cell type for study and modeling, or potential clinical application."[54] Very little of current fetal tissue research is germane to improving fetal health. The few theoretical surveys of fetal development, for example, when certain genes are expressed, have little to no practical benefit near term.

Meanwhile, ethically derived alternatives are growing in numbers and successes. Current advances in non-destructive stem cell research hold the promise to obviate the need for cadaveric fetal tissue in research and therapy. The NIH/FDA database reports over 3,300 approved ongoing or completed clinical trials using adult stem cells.[55] Worldwide, over 70,000 people receive adult stem cell transplants each year, for dozens of different conditions. Use of these therapies show no signs of slowing down, with well over one million adult stem cell transplants total.[56]

Rather than pursuing morally objectionable sources of human tissue for research, we would urge robust support for continuing life-saving and health-improving research and clinical applications using ethically-derived cells. We should not seek to restore our own bodies at the cost of using the tiny bodies of others, whose only offense was to be growing in the "wrong" womb at the "wrong" time. As a people, we deserve better, and as a nation we are called to be better.

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[53] Prentice, Written Testimony: Wisconsin Assembly Committee on Criminal Justice and Public Safety.
[54] Prentice, Written Testimony: Wisconsin Assembly Committee on Criminal Justice and Public Safety.
[55] Search term: http://www.clinicaltrials.gov/ct2/results?term=adult+stem+cell+transplants&type=Intr accessed February 28, 2016.
[56] Gratwohl A et al., One million haemopoietic stem-cell transplants: a retrospective observational study, Lancet Haematology 2, e91, March 2015.

A just society has no moral or other claim on electively aborted fetal bodies, organs, or tissues. Fetuses scheduled for termination by induced abortion are among the vulnerable, if not *the* most vulnerable, populations in the human family. As has been said by many leaders in many ways, a society will be judged by how it treats its weakest, most vulnerable members. Curbing the current practice of fetal tissue research would be a small but very significant step to honor that maxim.

Mrs. BLACKBURN. Thank you, Ms. Cunningham.
Professor Charo, you are recognized for 8 minutes.

STATEMENT OF R. ALTA CHARO

Ms. CHARO. Thank you, Madam Chairman, Ranking Member Schakowsky, and members of the Selective Investigative Panel. Thank you for allowing me to address you today on the question of fetal tissue research.

My name is Alta Charo. I am a member of the National Academy of Medicine, and was a member of the National Bioethics Advisory Commission from 1996 to 2001.

At present, I am the Warren P. Knowles Professor of Law and Bioethics, on the faculties of both the Law School and the School of Medicine & Public Health at the University of Wisconsin. But I would like to note for the record that I am not here to represent the University of Wisconsin or any of its units and that I have used my own personal funds in order to attend the hearing.

Madam Chair, fetal tissue has been used in research in this country since the 1920s, and NIH has funded it since the 1950s. It has been deemed ethical by Federal review bodies going back half a century and has been specifically authorized by Congress for funding for over a quarter-century precisely because it has saved the lives of countless people, including children and infants. It continues to be ethical, and it will continue to save lives.

In my view, supporting this research represents a commitment to helping today's patients and tomorrow's infants. I say this for three reasons: first, this research serves a compelling public health purpose; second, it operates with in a framework of State and Federal law; and third, support for it need not depend on one's views about abortion.

First, any discussion about fetal tissue must begin with its unimpeachable claim to have saved the lives and improved the health of millions of people. Indeed, almost every American has benefitted from this research in the form of vaccines for whooping cough, tetanus, chicken pox, and German measles. Diseases do not discriminate, and the beneficiaries of this research come from every place on the political, religious, geographic, and economic spectrum. You, yourselves, and those whom you love are undoubtedly among those who have benefitted from this research and whose lives have been made better.

When work began, nearly a century ago, no one knew precisely where the research would lead but, over time, it led to a Nobel Prize for developing a polio vaccine using cell lines from fetal tissue. Today's scientists also cannot say precisely which disease will benefit or when, but HHS says that fetal tissue continues to be a critical resource for developing vaccines against dengue fever, HIV and Ebola, and for research on devastating diseases such as Huntington's chorea and Alzheimer's.

And as of this year, Zika virus is also on that growing list. I would note for your attention that the CDC has posted information on its Web site on how to provide fetal tissue, including neurological tissue, preferably with the architectural structure intact, specifically for the purpose of studying and managing the Zika virus to prevent devastating birth defects in tomorrow's infants.

Now, some people may find the dispassionate, technical language used by professionals to be startling, but one should never mistake that for callousness, particularly when talking about men and women who have devoted their lives to improving all of our lives through medicine and science. And the use of cadaveric tissue and organs, ranging from mature hearts from adults to fetal tissue, can make some people uncomfortable about benefitting from material whose origins lie in complex situations, but it does not prevent us from accepting this life-saving gift.

Critics have overwhelmingly partaken of the vaccines and treatments derived from fetal tissue and give no indication they will foreswear further benefits. Fairness and reciprocity alone would suggest they should support the work or at least not thwart it.

Second, the use of fetal tissue in research has been specifically protected under American law for over 50 years, beginning in the 1960s with the Uniform Anatomical Gift Act, which was drafted specifically to include a provision allowing fetal tissue to be donated just as other cadaveric tissue is donated. And in 1974, President Ford had a commission look specifically at fetal tissue research, and that commission also found that it is ethical.

In the 1980s, President Reagan created the Human Fetal Tissue Transplantation Research Panel, chaired by the late Arlin Adams, a Republican, a retired Federal judge, an opponent of abortion rights, and the author of a book entitled "A Nation Dedicated to Religious Liberty." Like the earlier Ford commission, the Reagan panel found the research to be ethical, declared there was no evidence that fetuses were ever killed for the purpose of obtaining tissue and no evidence that it ever had any effect on decision-making or on the number of abortions performed in this country.

However, to guard against even that hypothetical possibility, current practice follows those recommendations, and discussion about donation takes place only after a woman has definitively decided to terminate her pregnancy. Indeed, the Reagan panel explicitly considered the question of whether the woman, herself, should be the one who gives consent and concluded that she was the party most interested in this topic and in this outcome and, therefore, she retained the moral authority to make this decision. They viewed any alternative to be even more problematic.

Fetal tissue research is subject to local oversight committees, State law, laboratory, tissue bank regulations, and various Federal laws addressing everything from the consent process, to collection and storage, to confidentiality of records.

Two separate GAO investigations have found no violations, and found no sale of tissue but only legally permitted reimbursement for expenses, and no violations have been found in any current investigations at either the Federal or State level.

Third, support for fetal tissue transcends the debate about abortion rights. Federal review has repeatedly found that the option to donate tissue has no effect on whether a woman will choose to have an abortion. That is one reason why the Congress passed by overwhelming, bipartisan margins that codified the recommendations of the Ford and Reagan committees, authorization to fund this research in particular.

Some of the most passionate supporters of that research recognized the difference between opposition to abortion rights and opposition to research using fetal tissue. Senator John McCain, for example, was quoted as saying, "My abhorrence for the practice of abortion is unquestionable. Yet, my abhorrence for these diseases and the suffering they cause is just as strong."

In this country, women have a constitutionally protected right to safe and legal abortion services. They make those decisions for their own reasons. And after that, some of them choose to donate the cadaveric fetal tissue to research. We gain nothing when we turn our back on the benefits of that research for people who are sick today or will be sick tomorrow, to say nothing of the irony of halting research that improves our chance of preventing miscarriages, preventing birth defects, and saving infant lives.

Thank you very much for your attention.

[The prepared statement of Ms. Charo follows:]

Testimony of
R. Alta Charo
before the Select Investigative Panel
of the
Energy and Commerce Committee
U.S. House of Representatives
2 March 2016
Washington DC

Madam Chair, Ranking Member Schakowsky, members of the Select Investigative Panel, thank you for allowing me to address you on research using fetal tissue. My name is Alta Charo. I am an elected member of the National Academy of Medicine, and was a member of the National Bioethics Advisory Commission from 1996 to 2001. At present, I am the Warren P. Knowles Professor of Law and Bioethics, on the faculties of the Law School and the School of Medicine & Public Health at the University of Wisconsin.

I would like to note for the record that I am here in my personal capacity as a scholar of bioethics. I do not represent the University of Wisconsin or any of its units, and have used only my own personal funds to come here to speak with you.

Madam Chair, fetal tissue has been used in research in this country since the 1920s, and NIH-funded since the 1950s. It has been deemed ethical by federal review bodies going back a half a century, and has been specifically authorized for funding by Congress for a quarter-century, precisely because it has saved the lives of countless people, including children and infants. It continues to be ethical and it will

continue to save lives. In my view, supporting this research represents a commitment to helping today's patients and tomorrow's infants.

I say this for three reasons. First, this research serves a compelling public health purpose. Second, it operates within a framework of state and federal law. And third, support for it need not depend on one's views about abortion.

First, any discussion of fetal tissue research must begin with its unimpeachable claim to have saved the lives and improved the health of millions of people. Indeed, almost every American has benefited, in the form of vaccines for whooping cough, tetanus, chicken pox and German measles. Diseases do not discriminate, and the beneficiaries of this research come from every place on the political, religious, geographic and economic spectrum. You yourselves, and those whom you love, are undoubtedly among those whose lives have been made better by this research.

When work began nearly century ago, no one knew precisely where the research would lead. But over time it led to a Nobel Prize for developing a polio vaccine using cell lines from fetal tissue. Today's scientists also cannot say precisely which disease will benefit, or when. But HHS says that "fetal tissue continues to be a critical resource" for developing vaccines against dengue fever, HIV and Ebola, and for research on devastating diseases such as Huntington's chorea and Alzheimer's. And as of this year, Zika virus is also on that growing list.

Some people may find the dispassionate, technical language used by professionals to be startling. But one should never mistake that for callousness, particularly when talking about men and women who have devoted their lives to improving all of our lives through medicine and science. And the use of cadaveric tissue and organs, ranging from mature hearts to fetal tissue, can make some people uncomfortable about benefiting from material whose origins lie in complex situations. But it does not prevent us from accepting this life-saving gift. Critics have overwhelmingly partaken of the vaccines and treatments derived from fetal tissue, and give no indication that they will foreswear further benefits. Fairness and reciprocity alone would suggest they should support the work, or at least, not thwart it.

Second, the use of fetal tissue in research has been specifically protected under American law for over 50 years. In the 1960s, the Uniform Anatomical Gift Act was drafted to include a provision that allowed fetal tissue to be donated just as other cadaveric tissue is donated for research and therapy. And in 1974, President Ford's commission on medical research also found that fetal tissue research is ethical.

In the 1980s, President Reagan created the Human Fetal Tissue Transplantation Research Panel, chaired by the late Arlin Adams: a Republican, a retired federal judge, an opponent of abortion rights and the author of a book entitled "A Nation Dedicated to Religious Liberty." Like the earlier Ford commission, the Reagan Panel found the research to be ethical, and declared there was no evidence that it had any effect on decision-making or on the number of abortions performed in this country.

To guard against even that hypothetical possibility, however, current practice follows its recommendations, and discussion about donation takes place only after a woman has definitively decided to terminate her pregnancy.

Fetal tissue research is subject to local oversight committees, state law, laboratory and tissue bank regulations, and various federal laws. These address everything from the consent process, to collection and storage, to confidentiality of records. Two separate GAO investigations found no violations, and found no sale of tissue, but only legally permitted reimbursement for expenses. And no violations have been found in any current investigations at the Federal or State level.

Third, support for fetal tissue transcends the debate about abortion rights. Federal review has repeatedly found that the option to donate tissue has no effect on whether a woman will choose to have an abortion. That is one reason why the Congress passed legislation by overwhelming, bipartisan margins that codified the recommendations of the Ford and Reagan committees, and authorized federal funding for this work. Some of the most passionate supporters recognized the difference between opposition to abortion rights and opposition to research using fetal tissue. Sen. John McCain, for example, was quoted as saying "My abhorrence for the practice of abortion is unquestionable. Yet, my abhorrence for these diseases and the suffering they cause is just as strong."

In this country, women have a constitutionally protected right to safe and legal abortion services. They make their decisions for their own reasons. And after that, some of them choose to donate fetal tissue to research. We gain nothing when we turn our backs on the benefits of this research for people who are sick today, or will be sick tomorrow—to say nothing of the irony of halting research that improves our chance of preventing miscarriages, of preventing birth defects, and of saving infants' lives.

Thank you.

Mrs. BLACKBURN. Thank you, Professor Charo.

And I will note that both of our female panelists came in with time to spare. And I think that is off to a great start.

I yield myself 5 minutes for questions, as we begin our question round. And again, I thank you all. I am kind of going to do a lightning round on questions, if you will. So, let us just, we will begin, Dr. Donovan, with you in responses and then just go right down the line.

So, first question: Do you think any business or clinic should sell fetal tissue for a profit?

Dr. DONOVAN. No.

Ms. CUNNINGHAM. I do not.

Mrs. BLACKBURN. Keep your mikes on, please.

Ms. CUNNINGHAM. I do not.

Ms. CHARO. It is against the law.

Mrs. BLACKBURN. Thank you all.

Number two: Do you think that fetal organs should be grown and harvested for transplant?

Dr. DONOVAN. No.

Ms. CUNNINGHAM. If they can be grown ethically, but not from the fetus itself.

Mrs. BLACKBURN. OK.

Ms. CHARO. I apologize, but I am not sure I understand exactly what you mean by "grown." Are you talking about getting pregnant deliberately in order to donate tissue? No, I would not think that that is appropriate. And in fact, the Reagan panel specifically worried about so-called directed donation and recommended that that be forbidden, and it is, under the law.

If you are talking about the creation of synthetic organs, which is currently under investigation and is something I believe my colleague Dr. Goldstein might even be talking about in the next panel, then I think that is something that needs a closer look and, without further information, I couldn't say, but it is probably a very good alternative.

Mrs. BLACKBURN. OK, thank you.

Question number three: Do you think fetal tissue should be used for cosmetics, cell lines to do taste tests for food, or for experiments that combine human and animal DNA?

Dr. DONOVAN. No matter how they are obtained, I would find these distasteful.

Ms. CUNNINGHAM. I agree with Dr. Donovan.

Mrs. BLACKBURN. OK.

Ms. CHARO. I think fetal tissue should be used in the same ways we use tissue from adults who have died, and that includes a wide range of uses. Some of the ones you mentioned are certainly not the ones that are the most compelling, but they are within the law at this time.

Mrs. BLACKBURN. OK.

Number four: If an alternative source of tissue to form cell lines exists, such as spontaneous miscarriages, do you think that is a more ethical approach?

Dr. DONOVAN. It does exist, and it is more ethical.

Ms. CUNNINGHAM. Yes, and panels have found that to be the case.

Ms. CHARO. It can be used, but it was found to be insufficient as a substitute for tissue from fetuses that were electively aborted. That was specifically considered by the Reagan panel and has been the subject of investigation since then, due to the kinds of causes that underlie miscarriages and often change the nature of the tissue. But certainly, it would be less controversial if one could find tissue that does not raise questions about the abortion debate. And avoiding controversy is preferable when it is possible, but not simply in order to avoid controversy at the expense of public health.

Mrs. BLACKBURN. Thank you.

And the fifth question: If vaccines exist that do not rely upon fetal tissue or cell lines, should consumers be given a choice?

Dr. DONOVAN. Actually, for the most part, those vaccines do exist. There are a few still left over from the cell lines started in the '60s to which there is no alternative. Many people have asked that an alternative be developed. That wasn't a "yes" or a "no," was it?

Mrs. BLACKBURN. That is an answer, and that is perfectly fine.

Dr. DONOVAN. Thank you.

Mrs. BLACKBURN. I appreciate that, and I will take that elaboration.

Ms. CUNNINGHAM. I think parents and patients should be aware of the source of the vaccines they are using. At least, it should be available for their information for them to make their own choice about whether to use one that is derived ethically or unethically.

Ms. CHARO. That information is available on the Internet. I have no problem with the idea of saying that people have the right to have as much information as possible and to make choices for themselves.

I would note in passing that with regard to the vaccines that have no current alternatives, the Vatican has said specifically that although they would wish that there would be other alternatives available, that parents who wish to protect their children by using vaccines that were derived using fetal tissue should feel free to go ahead and do so and put their children's interests ahead of all other concerns.

Dr. DONOVAN. Madam Chairman?

Mrs. BLACKBURN. Yes?

Dr. DONOVAN. Could I offer a correction to that one? I hesitate to have Ms. Charo corrected on the interpretation of Vatican statements but, in fact, that isn't what the Vatican said. What they actually said was because the danger to pregnant women would be so great and their fetuses that children could be immunized with this, not so much for the protection of the children themselves from getting rubella but from spreading it to pregnant women and their babies.

Mrs. BLACKBURN. OK. Professor Charo, did you have anything else to add?

Ms. CHARO. No. I am happy to accept the notion that their concern was not for the child who is getting vaccinated but for the future children who might be affected when pregnant women get infected from the unvaccinated child.

Mrs. BLACKBURN. OK. Dr. Donovan, anything else?

Dr. DONOVAN. It wasn't a lack of concern for children getting vaccinated. Vaccines—all us pediatricians think vaccines are wonderful things and everybody ought to get lots of them but, in fact, the reason that such a moral change could occur, such an exception could be offered, was because it was truly life or death for the pregnant woman's baby, and that is who needed the protection and, therefore, the exception could be made.

They still are quite in favor of other vaccinations.

Mrs. BLACKBURN. Thank you. My time has expired.

At this time, I yield 5 minutes for questions to Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you. The Los Angeles Times reporter and columnist Michael Hiltzik wrote in September of last year that it "would be a moral outrage" if fetal tissue research became "collateral damage in the campaign against Planned Parenthood."

He also quotes you, Professor Charo, as saying, "We have a duty to use fetal tissue for research and therapy. And that duty includes taking advantage of avenues of hope for current and future patients, particularly if those avenues are being threatened by a purely political fight."

So, let me ask you, can you explain, Dr. Charo, the view that there actually is an affirmative duty to use available avenues of research? And if you could, please address how this might come into play with the Zika virus and research to understand and find a solution to what the World Health Organization has classified as a "public health emergency of international concern."

Ms. CHARO. Thank you, Ms. Schakowsky, for the question.

The United States health policy is directed at improving the quality of public health. It is considered a compelling purpose under every possible regime of both law, legislative and judicial. And in this particular instance, this research has proven itself capable of preventing millions of diseases and has shown tremendous promise across a range of illnesses.

From my perspective, if we are dedicated to improving the health and welfare of our population, this means pursuing avenues of research that might improve our resistance to disease or our ability to manage or even cure diseases. Now, that is always balanced against other interests. And I understand and appreciate the depth of concerns about abortion that are expressed here at this table and by many other Americans. But, because this research in no way affects the number of abortions, it seems to me that we are balancing a compelling public health need against what is simply a gesture of sentiment, respect, political position, or other kind of nonconcrete effect against the possible cure for diseases.

Now, with regard to Zika, I think it brings it really into focus because, right now, we are struggling to understand exactly how the Zika virus operates, how it is that it can be transmitted through the placenta to the fetus, how it is that it can affect fetal development at different stages of gestation, and how we can understand what kinds of outcomes it will have. For that, we need to actually look at the tissue available after every stage of gestation where there actually has been a termination of pregnancy, whether through miscarriage or through elective abortion.

If we don't do that, we are facing, as you said, a global emergency in which pregnant women will be forced to choose between

risking the birth of a child with devastating effects or, in fact, terminating her pregnancy; irony being that the absence of this fetal tissue research might lead to more pregnancy terminations than anybody has ever contemplated up until now. I think we need to look very hard at the unintended effects of restricting this research.

Ms. SCHAKOWSKY. So, are you saying, then, that without fetal tissue research we can't really understand the effect on fetuses?

Ms. CHARO. Because I am not a research scientist, I don't want to answer definitively but I can say that looking at the NIH Web site, looking at the CDC Web site, and looking at the information put out by other national governments, it seems clear that there is a global consensus it is very important to study exactly how the virus operates, both at the earliest and latest stages of pregnancy in order to understand how we might either stop it or treat it.

Ms. SCHAKOWSKY. Let me also ask you, if the remains of the fetus are not used for fetal tissue research, what happens to it?

Ms. CHARO. The tissue is discarded. There are a variety of methods; some involve burial, others involve cremation. There are a few States that have very specific legislation about the management of fetal remains. But they are not used in any way that is helpful to anybody outside of the possibility of using them for this research.

Ms. SCHAKOWSKY. And let me ask you a question, since we are talking about ethics: Does the fact that fetal tissue research is now under attack and at risk of being shut down warrant our moral outrage?

Ms. CHARO. I am outraged at the idea that we would sacrifice valuable research and that we would gamble with the lives of patients today and tomorrow—gamble with our own lives and gamble with the lives of the people in our family and in our communities—because we are trying to fight a deeper battle about our common view on the moral and legal status of the fetus. Again, I can only say again and again that the number of abortions in the United States will be unaffected by the outcome of this discussion about whether to use the remains for research.

The only thing we know is that we will lose the benefit of the research for people who do in fact get sick.

Ms. SCHAKOWSKY. I thank you so much.

And Madam Chair, I seek unanimous consent to enter into the record the Los Angeles Times article that I have been discussing titled "Planned Parenthood and the Cynical Attack on Fetal Tissue Research."

[The information appears at the conclusion of the hearing.]

Mrs. BLACKBURN. So ordered.

Ms. SCHAKOWSKY. Thank you.

Mrs. BLACKBURN. The gentlelady yields back. At this time, I recognize Chairman Pitts, 5 minutes.

Mr. PITTS. Thank you, Madam Chairman.

First of all, Dr. Charo's written statement that the success of fetal tissue is "unimpeachable" is not completely accurate. The Nobel Prize given to Enders, Weller, and Robbins in 1954 was for showing that polio virus could be grown in fetal tissue in the laboratory, not for developing the polio vaccine. In fact, the original

Salk and Sabin vaccines were raised in monkey tissues, not human fetal tissue.

And she conflates the use of fresh aborted fetal tissue with the use of fetal cell lines. And while a few cell lines which did originate from an abortion were used in the past for production of some vaccines, only a few modern vaccines utilize these old fetal cell lines, and none use fresh aborted fetal tissue. In fact, the CDC and other leading medical authorities have noted that "no new fetal tissue is needed to produce cell lines to make these vaccines now or in the future." The new successful vaccine against Ebola virus announced last summer was made using monkey tissue, not fetal tissue or fetal cell lines.

So, Dr. Donovan, looking at modern vaccines, do you see any need for use of fresh aborted fetal tissue for vaccine production?

Dr. DONOVAN. I think your statement was absolutely accurate, that yes, these have been of use in the past. There are other cell lines. There are other means of producing vaccines. And so, there is no need to use fetal tissue to produce new cell lines for vaccine production.

Moreover, I think it may be a bit disingenuous to say that millions of lives have been saved because these vaccines were produced in the past. Millions of doses have been given and millions of infections have been prevented. Most of those would not have resulted in serious injury to the person immunized or death, certainly. That doesn't mean we shouldn't still be immunizing.

Mr. PITTS. Thank you.

Dr. DONOVAN. Thank you.

Mr. PITTS. Thank you. At what point—and you can continue, Dr. Donovan. At what point in human development does science show one is a human being, and why is this?

Dr. DONOVAN. Well, we really have to go back to one's definition. If we are talking about is it human in terms of having a full complement of cells that develop continually into fully grown adults, that happens at the zygote stage.

Mr. PITTS. Well, let me go a little further. Is there a point in the baby's gestation at which researchers most want fetal tissue for research, and why is this?

Dr. DONOVAN. And that I am not sure that I can answer accurately. So, I won't.

Mr. PITTS. All right. Is there any scientific evidence that unborn babies at a later stage feel pain, and should the knowledge of a baby's ability to feel pain by certain points in development affect the ethics surrounding fetal tissue collection from induced abortion?

Dr. DONOVAN. I think the evidence for fetal pain is very strong, and we are seeing good evidence at 18 to 20 weeks of gestation that fetuses can respond with pain responses. And I think, no matter how you feel about a fetus—you can accept its humanity, you can reject its humanity—but we wouldn't allow kittens and puppies to be harmed or put to sleep without keeping them out of pain. I don't think we should do that for fetuses, either.

Mr. PITTS. Ms. Cunningham, did you want to add something to that?

Ms. CUNNINGHAM. No, thank you.

Mr. PITTS. All right. Well, I appreciate your testimony about unborn children are the most vulnerable in the human family, and they are deserving of respect and protection. Yet, we see they are legally—they are destroyed in abortions and either thrown away or traded like a commodity, and it is our duty to protect them, not facilitate the market for their case.

My time has expired. Mrs. Chairman, I yield back.

Mrs. BLACKBURN. And at this point, I yield 5 minutes to Ms. DeGette for questions.

Ms. DEGETTE. Thank you very much, Madam Chair.

I want to thank all the members of the panel for coming and presenting your different perspectives, because I think talking about ethics in these situations is important.

Dr. Donovan, I believe you testified—and I only have 5 minutes, so "yes" or "no" will suffice most of the time—I believe you testified that you are not a research scientist. Is that correct?

Dr. DONOVAN. Although I have been——

Ms. DEGETTE. A "yes" or "no" will work. You are not a research scientist.

Dr. DONOVAN. Yes.

Ms. DEGETTE. Thank you.

And Ms. Cunningham, you are an ethicist. Is that correct?

Ms. CUNNINGHAM. Yes, in the most part.

Ms. DEGETTE. Yes. Now, Dr. Donovan, I believe that you are philosophically opposed to abortion. Is that correct?

Dr. DONOVAN. Yes.

Ms. DEGETTE. And Ms. Cunningham, you are also philosophically opposed to abortion, right?

Ms. CUNNINGHAM. Yes.

Ms. DEGETTE. Now, Dr. Donovan, do you believe that fetal tissue research should be banned in this country? Yes or "no"?

Dr. DONOVAN. It depends on where you get the tissue. No.

Ms. DEGETTE. So, you don't believe it should be banned.

OK, what about you, Ms. Cunningham?

Ms. CUNNINGHAM. I can't give a yes-or-no answer to that. Some should be banned.

Ms. DEGETTE. Some should. Well, which should be banned?

Ms. CUNNINGHAM. That that is unethically derived—that uses unethically derived tissue.

Ms. DEGETTE. OK, tell me which fetal tissue research is ethically derived.

Ms. CUNNINGHAM. That which uses fetuses that are donated after an ectopic pregnancy is removed or a stillbirth or a miscarriage.

Ms. DEGETTE. OK. So do you think that fetal tissue research from abortions should be banned?

Ms. CUNNINGHAM. In its current practice, yes.

Ms. DEGETTE. And Dr. Donovan, thank you for helping me clarify. Do you think fetal tissue from abortions should be banned?

Dr. DONOVAN. Yes.

Ms. DEGETTE. Thank you. Now, Dr. Donovan, you testified that we have cell lines that have been developed over the last 50 years from fetal tissue research. Correct?

Dr. DONOVAN. Correct.

Ms. DEGETTE. Is it your position, since those cell lines were developed from aborted fetal tissue 50 years ago, that since it was so long ago, it is OK to use that research now? Is that what you were trying to tell us?

Dr. DONOVAN. In the absence of alternatives, then it can be acceptable when it is far removed.

Ms. DEGETTE. So, because the abortions were a long time ago, it is OK that we use that tissue now, correct?

Dr. DONOVAN. It is a little more complex than that.

Ms. DEGETTE. I see. Now, you also testified that—I believe, yes, it was you who talked about the Tuskegee and the Mengele experiments. Do you make fetal tissue research from abortions equal to those experiments?

Dr. DONOVAN. I think that we need to be very careful that we don't do that.

Ms. DEGETTE. Do you think that they are equal? "Yes" or "no"? "Yes" or "no"?

Dr. DONOVAN. Maybe.

Ms. DEGETTE. Thank you.

Now, I want to talk with you, Ms. Charo, for a minute. You testified about your view of the ethics of fetal tissue research from abortions. You mentioned the NIH panel on human fetal transportation research during the Reagan administration. Is that correct?

Ms. CHARO. Yes, I believe it was HHS and not NIH specifically, but yes.

Ms. DEGETTE. OK, HHS. And in fact, that blue ribbon panel unanimously endorsed the position that fetal tissue research is not only ethical but should proceed. Is that correct?

Ms. CHARO. I believe the vote was 19 to zero.

Ms. DEGETTE. Yes, it was unanimous. And the chair of that commission was actually opposed to abortion. Is that correct?

Ms. CHARO. Yes.

Ms. DEGETTE. And the reason was, as you testified a minute ago, because abortion is legal in this country, and so people thought we should be able to give the opportunity to people who had made that legal choice to have an abortion to then donate that tissue to help save other lives. Is that correct?

Ms. CHARO. Yes.

Ms. DEGETTE. Because as you testified, the alternative when somebody chose to have an abortion, if they did not donate that tissue, was the tissue would be destroyed as medical waste. Is that correct?

Ms. CHARO. Yes, it is.

Ms. DEGETTE. And that, in fact, is why many people do make the ethical choice to donate the tissue. Is that right?

Ms. CHARO. I believe so.

Ms. DEGETTE. Now, I wanted to ask you one more thing, which is from an ethical standpoint, do you think that it makes any difference when cell lines were developed, whether it was 50 years ago or last year from tissue from abortions?

Ms. CHARO. In this circumstance, I do not think so, because the prospect of research in the future or the existence of research in the past is equally indifferent to the question of whether a woman

would decide to have an abortion. That decision is not affected by the research or the prospect of it.

Ms. DEGETTE. Thank you. Thank you very much, Madam Chair.

Mrs. BLACKBURN. The gentlelady yields back.

At this time, I recognize Mrs. Black for 5 minutes.

Mrs. BLACK. Thank you, Madam Chair, and I want to thank all the panelists for being here today.

I want to begin by saying that I spent my entire career as a nurse. I worked in the emergency room most of that time. And it was my responsibility when I was in the emergency room, before we had the organ procurement organizations, to come and talk with the family members. It was my responsibility when someone was deceased to look them in the eyes and ask them if they would consider donating their family member for research or transplantation. It was a very sensitive time. And I have got to tell you that as I think about those times, I can actually see the eyes in the people that I asked this of. And one of the things that I will always remember is the dignity and the respect for those family members.

Families—actually, there was a report done in Office of Inspector General—and if I may insert this into the record—that looked at informed consent in tissue donation and what the expectation and the realities were of these family members.

And here are the things that were found in there, and I don't think it will surprise any of us because if we have someone we love that dies either expectedly or unexpectedly, it is a very traumatic thing: What organs will be procured? Will the body be treated with respect? And special care to ensure that the gift is used for the stated purpose. Those are the three main things that were found in both this report and also my experiences.

Very tender times and, as I say, a dignity of life and respect for that. I am curious that we don't have that same dignity and respect for the life of what we call tissue and fetus and embryo. This is a baby. I think Ms. Charo mentioned these are the remains. Tissue is discarded. This is not tissue. This is a baby. You don't get a brain, a liver, a kidney, all of these organs from a tissue. It is a baby. It is not a blob of tissue.

Now, what I want to go to is, if we could put up an Exhibit F.

In these documents, documents were produced to the panel by a leading university to show that a researcher sought from a tissue procurement business, quote, a first trimester human embryo, preferably around 8 and up to 10 weeks of gestation. And I think you all may have that in front of you, but the document is Exhibit F, and this is what it looks like. It actually says "Doctor," and the name of the doctor is blacked out, "at the University of —— would request a first trimester human embryo, preferably 8 to 10 weeks of gestation. We have ordered tissue before, so our information should be on file. Please let us know if this tissue is available."

This is not dignity. This is not dignity. This is not respect for human life. I want to ask the panelists, Have we reached a point in our society where there effectively is an Amazon.com for human parts, including entire babies? And I would like to ask our panel for their opinion on this email and the notion of obtaining potentially entire embryos on demand.

Dr. Donovan, would you like to address this?

Dr. DONOVAN. I, personally, find that it shocks my conscience, and I think it should shock the conscience of the Nation. I think you are absolutely right, we have commodified what have been referred to as the products of conception, meaning babies and baby parts. And yes, they are for sale, supposedly just to cover one's costs, but those costs seem to be quite variable. But even if they were given away free, it is shocking to be ordering what you want: Can I have a boy fetus or a girl fetus, or a brain, or a heart, or a liver? This is totally in distinction to the honorable transplantation industry that is lifesaving and shows great respect for the donors.

Mrs. BLACK. Ms. Cunningham?

Ms. CUNNINGHAM. I think what we need to pay attention to here is not is this somehow increasing abortion. My concern is that researchers have come to count on induced abortion for their research. And one of the articles that I cited in my written testimony shows that they say that liver from induced abortions is widely available and is a promising source. What have we come to where researchers need induced abortion to do their research? Wouldn't it have been better if we had banned this at the beginning and use the creative minds that we have to find ethical alternatives?

Mrs. BLACK. Ms. Cunningham, I hate to cut you off. Thank you.

And I just have one brief comment to make because my time is going to end here in just a second. I believe that we should give the same information and dignity to these young women that are making these decisions, and I believe that it should be a more informed and educational decision that they are making, and I don't believe that is happening currently.

I yield back the balance of my time.

Mrs. BLACKBURN. The gentlelady yields back.

Ms. Speier, you are recognized for 5 minutes.

Ms. SPEIER. Thank you, Madam Chair, and thank you all for your participation today.

You know, today I feel like a time traveler, not a Member of Congress. Perhaps we have been transported back to 1692 to the Salem witch trials, where fanatics persecuted and murdered innocent people who had committed no offenses. Or maybe we have been transported back to the Red Scare, where at least 10,000 Americans in many professions around this country lost their livelihoods due to the reckless and disgraceful actions of the House Un-American Activities Committee and the infamous Senator Joseph McCarthy, who eventually went after an Army General Counsel, Mr. Welch. And Mr. Welch finally put down Senator McCarthy by saying, "Have you no decency?"

Unfortunately, this time, those being burned at the stakes are our scientists, who hold future medical breakthroughs in their hands. They are joined by brave women's healthcare providers who are simply trying to care for their patients. Meanwhile, David Daleiden and his associate, Sandra Merritt, fraudulently created the Center for Medical Progress and they were indicted in Texas by a grand jury for actual illegal activities. They are the reason why we are here today. Illegal conduct by two people, they have now been indicted, and that has been the creation of this committee.

And I have here a poster that shows what they have been indicted for. They have been indicted for two felonies for tampering with Government records. In California, they are being investigated for any number of felonies, including misrepresentation of one's company to the IRS, felonies for fraud in creating fake drivers' licenses, and credit card fraud identity. And a judge in California has made this statement in granting a motion for a preliminary injunction by saying, "Defendants engaged in repeated instances of fraud, including the manufacture of fake documents, the creation and registration with the State of California of a fake company, and repeated false statements in order to infiltrate and implement their Human Capital Project. The products of that Project—achieved in large part from infiltration—thus far have not been pieces of journalistic integrity, but misleadingly edited videos and unfounded assertions."

So my question to you, Dr. Donovan, is this: You are an expert on ethics, as is Ms. Cunningham and Ms. Charo. Do you think it is appropriate to conduct oneself in that manner? Is that ethical? Is that moral? "Yes" or "no"?

Dr. DONOVAN. Most ethical and moral questions are not yes-and-no questions.

Ms. SPEIER. Well, we have been asking yes-and-no questions this morning.

Dr. DONOVAN. I have noticed that. I have noticed that. It doesn't always help one unpeel the onion in order to get to the truth. So, if you want a "yes" or "no," I am not quite sure how to answer that as a "yes" or "no."

Where is the greater damage? I am not an expert on journalistic ethics, and I am certainly not an expert on the law. I am glad that carrying a false driver's license isn't a felony everywhere, or many college students would end up in jail.

Ms. SPEIER. Do you think committing fraud is ethical?

Dr. DONOVAN. Of course, fraud is not ethical.

Ms. SPEIER. All right.

Dr. DONOVAN. Neither is what was being investigated.

Ms. SPEIER. Ms. Cunningham.

Ms. CUNNINGHAM. And the specific question?

Ms. SPEIER. Is committing fraud ethical?

Ms. CUNNINGHAM. As a broad statement, one would say it is not ethical, but I am not answering the specific question about the conduct of David Daleiden.

Ms. SPEIER. So, you think Mr. Daleiden is ethical?

Ms. CUNNINGHAM. As Dr. Donovan said, that is a very broad statement.

Ms. SPEIER. All right, thank you.

Ms. CUNNINGHAM. I can't answer it in the way that you are asking.

Ms. SPEIER. Professor Charo?

Ms. CHARO. I think the attempt to deliberately create distorted videos for political purpose and to tarnish an organization that helps millions of women was profoundly unethical and destructive.

Ms. SPEIER. I thank you, and I yield back.

Mrs. BLACKBURN. The gentlelady yields back.

At this time, Dr. Bucshon, you are recognized for 5 minutes.

Mr. BUCSHON. Thank you. First of all, I just want to say I was a practicing cardiovascular and thoracic surgeon for 15 years prior to coming to Congress. And thank you, all the witnesses, for being here.

I also want to say it is totally appropriate to reevaluate and examine ethical issues that have been examined in the past. Times do change. And so I know some of the narrative has been that in the past people have looked at these issues and come to conclusions but, in health care, particularly, I think, it is important that we occasionally reexamine these issues.

The other thing is, based on some of the comments of my Democratic colleagues, I am not sure what everyone is so afraid of, because this type of discussion about ethics is totally appropriate and we don't have a preconceived outcome.

And I would also just remind everybody in the crowd that charges and indictments don't mean convictions and guilt.

So, with that, I would like to go to Exhibit B–1 and go over some emails, and you may have those. And the first is a customer—this is between a tissue technician and a customer. I am going to walk you through this:

"We are now ready to include the skull so if you would please include that in our order for tomorrow that would be great. ... If there is a case tomorrow could you please have someone contact me with the condition of both the long bones and the calvarium"—which is the head—"and I will be happy to let you know if we would like one or both." Four minutes later, the technician responds, "I will be happy to do that."

Exhibit B–2, the customer replied a day later: "Just wanted to check in and see if there were any cases within our gestational range for today?" The technician responded 4 minutes later: "There is one case currently in the room. I will let you know how the limbs and calvarium look to see if you are able to take them," which means they are discussing actively during the abortion itself.

Three minutes later, the client said, "Great, thank you so much."

Exhibit B–3, after the abortion is performed, the technician tells the customer the calvarium, the head, "is mostly intact with a tear up the back suture line, but all pieces look to be there. The limbs, one upper and one lower are totally intact, with one upper broken at the humerus"—which is the upper arm bone—"and one lower [limb] broken above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply." Five minutes later, the customer replies, "That sounds great. We would like both of them. Please send them our way. Thanks again."

The technician says, "Limbs and calvarium will be there" at 3:30 to 4:00.

And we will hear later in testimony and there is evidence to show the technicians are partially paid by the number of body parts that they could get.

So, given that, do these emails raise any ethical issues? And if so, what are they? Dr. Donovan.

Dr. DONOVAN. Once again, I think that what we are seeing is a total lack of respect for the dignity of the human body, in this case, because as we have already pointed out, not only are these humans but these are human body parts. Otherwise, no one would be inter-

ested in them. But to order them piece by piece like you would order a McDonald's hamburger, I find discouraging and shocking.

Mr. BUCSHON. Ms. Cunningham?

Ms. CUNNINGHAM. I do find a number of serious ethical problems. One being, apart from the question of abortion itself, I think this completely fails to isolate abortion from the decision about the fetal tissue and consent to use the fetal tissue. In what we see here, there is no indication of consent prior to this procedure or for these specific parts to be excised.

Mr. BUCSHON. And in fairness, that could have occurred earlier, I guess.

Ms. CUNNINGHAM. It could. I just said there is nothing here to indicate that.

Mr. BUCSHON. Ms. Charo?

Ms. CHARO. I would just like to add a little bit of context because exactly the same kind of language would be used if we were talking about people ordering tissue from adults who had died and were now having their bodies used for tissue and organ recovery. It is the same kind of clinical, dispassionate language that is deeply upsetting to many of us who are not in that world and are not familiar with that. As you, as a physician, have said, there is a world of difference in how we talk about things. And——

Mr. BUCSHON. OK, my time is running. I appreciate that.

Ms. CHARO. Yes, and there is a world of tissue transplantation and tissue research with adult tissue out there that is enormous and is very little different from what we are seeing here. So, just a little context of how this all works.

Mr. BUCSHON. Sure. And I would like to say, as a physician, during my training I spent a lot of time on transplantation, both talking to recipients and also family members of people who were in an unfortunate situation making a decision on behalf of their loved one to donate organs.

But, you know, I think that talking about a human being like this, just the mere fact that the arm was broke and the leg was broke, and they are talking about the head separately of a human being is something to me that is pretty hard to take, as a physician.

I yield back.

Mrs. BLACKBURN. The gentleman yields back.

Ms. DelBene, you are recognized for 5 minutes of questions.

Ms. DELBENE. Thank you, Madam Chair. And thank you to all the witnesses for being with us today.

I would like to start by dispelling any misconceptions about this hearing and this committee's investigation. It is definitely not objective or impartial in any way. This taxpayer-funded committee was created by Republicans more than 4 months ago, after a group of anti-choice extremists made a series of false, unsubstantiated allegations about Planned Parenthood. Since that time, four different congressional committees and a grand jury tried and failed to uncover any evidence of wrong-doing, and their anti-choice accusers have been indicted on felony charges.

Meanwhile, the majority has deliberately ignored this growing body of evidence and has clearly decided to continue spending tax-

payer dollars to attack women's health and intimidate healthcare providers across the country.

Now, in the committee's first hearing, the majority would like our constituents to believe we are conducting an objective hearing on medical research, and that couldn't be further from the truth. What we are really doing is reopening a long-settled debate about research to further a broader political agenda against a woman's right to choose. And if their attacks on science succeed, then we will all pay the price because nearly every American has benefitted from research conducted with fetal tissue. That is how we developed the first-ever polio vaccine. It is how we make vaccines for rubella, chicken pox, and shingles. It is how scientists are pursuing new treatments for heartbreaking diseases like Alzheimer's and HIV. And it is all done in full compliance with the high ethical standards recommended by President Reagan's blue ribbon panel in 1988, which were passed by Congress with broad bipartisan support.

So, as someone—I started my career doing medical research, and I know that research using all human tissue is subject to ethical and legal standards. Professor Charo, do you agree with that?

Ms. CHARO. I do.

Ms. DELBENE. And Professor, do you think it is appropriate to use ideology about women's rights to shape the roles that guide scientific research? And why or why not?

Ms. CHARO. No, I am very, very unhappy at seeing a debate around abortion turn into a debate around scientific research. That is not to say I am happy about the debate about abortion, either, because I also find it really offensive to imagine that women are incapable of making their own decisions about whether to have an abortion and whether or not to donate the tissue.

But, for sure, while that is going on, scientific research ought not be halted or hindered simply as an attempt to demonstrate one's opposition to abortion rights in an either political or public relations manner. It doesn't change anything, and I don't think that the public should be made a victim of those abortion wars.

Ms. DELBENE. Can you speak a little bit about the role of Institutional Review Boards in providing oversight on the use of human tissue in research? How do they help ensure that research is compliant with ethical and legal standards?

Ms. CHARO. So, like Dr. Donovan, I have been a member of an Institutional Review Board off and on for many years. And those Boards look at a variety of things, starting with how it is that people are first approached and asked about whether or not they would like to participate in research or, in this case, to donate materials. It looks at the nature of the conversation that will be had, the documentation because of course what is on paper is not the extent of the conversation, it is simply the minimum number of items that need to be documented as far as the consent form goes.

It looks at whether or not, in the end, there has been compliance. There are often research monitors that will observe a certain number of interactions in order to ensure compliance. There is an annual review that is required for each research protocol, and sometimes reviews are done more frequently, depending upon the protocol.

The Institutional Review Board is made up of a variety of people from both scientific and clinical and nonmedical backgrounds, including law, ethics, religious studies, and members of the community who can reflect the local community culture in those discussions.

Ms. DELBENE. And that has been something that also the blue ribbon commission looked at and made sure that those boards were appropriate, and that was part of that debate that they had and decision they had from the commission?

Ms. CHARO. Yes, Institutional Review Boards are actually required by law. It begins with the use of Federal funds that will trigger such a requirement or the research into things that are regulated by the Food and Drug Administration, but most major research institutions now have extended that review beyond the legal requirements in order to give what is called a Federal-wide assurance of all research at that institution, complying with these same rules, even where not legally necessary.

Ms. DELBENE. Thank you so much. I yield back, Madam Chair.

Mrs. BLACKBURN. The gentlelady yields back.

Dr. Harris, you are recognized, 5 minutes.

Mr. HARRIS. Thank you very much. You know, I am a physician and I was a physiology researcher. I actually did fetal research, but it was of fetal sheep of cerebral blood flow. And I also was a human principle investigator who actually had to file IRB applications.

I don't intend to litigate the use of fetal tissue, because I suspect you all agree about this. And I am just going to—Dr. Donovan and Ms. Cunningham, when you said the question about fetal tissue, I assume you support fetal tissue research from spontaneously aborted fetuses. Correct?

Dr. DONOVAN. Correct.

Mr. HARRIS. Correct?

Ms. CUNNINGHAM. Yes.

Mr. HARRIS. OK, so we all agree. Let's all agree this is not litigating fetal tissue research. We all agree it should be done.

Now, Dr. Donovan, let me just say I was fascinated by your—because what we are talking about here is consent and whether IRB consent and patient consent, whether that is all adequate. The idea that when you are a guardian of someone that you are qualified to give consent because you have the global best interest of that person in mind has to be brought into question when it is an elective abortion. I mean, it just has to be.

And with regards to the millions of people saved by fetal tissue research, we are all talking about the vaccines, the two cell lines. One cell line—interesting, a female child aborted because the family was too big. I would proffer that that mother, that if you gave that child and that child could somehow give consent, they would never consent to that abortion. The second one is a male which was aborted for, quote, "psychiatric reasons." Now, when I had to get IRB approval on a patient, I had to be careful about approaching a patient with psychiatric illness because a lot of people feel they don't have the ability to give consent. So, it was a very good point you made.

Let me just talk a little bit about an IRB question, specifically for you, Dr. Donovan. Is the source of fetal tissue or how it is ac-

quired a valid question that an IRB should have answered before they approve a project?

Dr. DONOVAN. It is not only a valid question, it is asked and has to be answered. Some institutions would absolutely forbid its use.

Mr. HARRIS. So, that if there were an instance where the application was, let us say, massaged a little bit, so that it was a little unclear what the source was, in an attempt to bypass that, that would really bypass the intention of an IRB. Is that right? For instance, if you didn't call it exactly what it was or what could be readily identified as the source.

Dr. DONOVAN. Yes, you clearly know what you are talking about. And in fact, would that occur, the investigator would be in trouble with the IRB. They would be called in and questioned about it.

Mr. HARRIS. Sure. Let's look at Exhibit A–3, which is a commonly used form for fetal tissue donation that was uncovered through discovery by the committee.

Ms. Cunningham, when I had to get consent from patients because we obtained human tissue at a cesarean section, human uterine tissue, we normally exactly described the tissue and then really kind of exactly described what it was going for. It could be global. It could be OK, in this case, it was to study uterine myocytes and their effect on preterm labor. Do you find anywhere on that form where it—I will tell you I don't see anywhere where it asks specifically what tissue it is. In the case brought up by Dr. Bucshon, I assume that in that abortion, they didn't go to the mother before and say, "Oh, by the way, we are going to collect an arm and a leg, and we are going to do it for this kind of research." Is that something you think part of informed consent ought to be, that you actually know where this tissue is going and for what?

Ms. CUNNINGHAM. Yes, and I am not the only one. If you look at elements of fetal tissue donation consent in other contexts, it is quite specific on what is being discussed with the prospective donor or their family.

Mr. HARRIS. Absolutely.

Ms. Charo?

Ms. CHARO. I——

Mr. HARRIS. You point to the gentlelady—no, I have to ask the question.

Ms. CHARO. Oh, I am sorry.

Mr. HARRIS. To the point from the gentlelady from Tennessee, when my wife passed away a year and a half ago, I got a call from the Medical Examiner's Office requesting donation of her brain. It was a tough call, but they specified one tissue and they specified what was going to be done with it.

Now, you look at Exhibit A–3, and then you look at Exhibit C–1 and C–2, which are actually what various anatomical donation forms used by States, it is strikingly different. Strikingly different.

Do you think that it really ought to be included when you ask someone, a woman, to donate the fetal tissue that you perhaps suggest specifically what it is going for and what the specific tissues to be used are going to be, if the person knows or should they make a best effort to know?

Ms. CHARO. I am not sure. I think——

Mr. HARRIS. Thank you very much. I yield back.

Mrs. BLACKBURN. The gentleman yields back.

Mrs. Watson Coleman, you are recognized for 5 minutes for questions.

Mrs. WATSON COLEMAN. Thank you, Madam Chairman. I have a question for Dr. Donovan and for Ms. Cunningham, and I would appreciate "yes" or "no."

I need to understand. Are you suggesting that it is more moral and more ethical to discard fetal tissue that is available even after an abortion that a woman decided to have, rather than use it for medical research purposes? Is that a "yes" or a "no"?

Dr. DONOVAN. That is not a "yes" or a "no."

Mrs. WATSON COLEMAN. Is that a "yes" or a "no"? Let me ask it this way: Do you believe that fetal tissue that has been derived from a woman's decision to abort should be used for medical purposes or not? Is that a "yes" or a "no," sir?

Dr. DONOVAN. That is not a yes-or-no question.

Mrs. WATSON COLEMAN. Ms. Cunningham, do you agree or disagree that fetal tissue that is available as a result of a woman deciding to have an abortion should be used for medical research purposes or discarded?

Ms. CUNNINGHAM. I am sorry, what am I——

Mrs. WATSON COLEMAN. What is it that you all don't understand? I understand——

Dr. DONOVAN. Would you like an answer to your question?

Ms. CUNNINGHAM. "Yes" or "no" can't answer used or discarded. I am sorry.

Mrs. WATSON COLEMAN. Used for medical research purposes or discarded and not used for any purpose—eliminated, trashed, thrown away—as opposed to used for medical research purposes to find whether or not a cure could be found for Zika, a cure could be found for some other disease. Do you believe that it is moral to discard that tissue rather than use it? Is that a clear enough question?

Ms. CUNNINGHAM. Thank you. Because I am under oath, I cannot answer a yes-or-no question. What I can say is that it is currently being practiced. I do not believe it is ethically possible to do so.

Mrs. WATSON COLEMAN. Dr. Charo, may I please have your sort of sense of what you just heard from both of these individuals with regard to the use or the discarding of fetal tissue that is a result of a woman's decision to have an abortion?

Ms. CHARO. I will stand corrected because I am speaking for other people, but I think I heard that they are uncomfortable with both outcomes. But given only those two choices, they would discard rather than use for fetal tissue, for a variety of reasons having to do with why they oppose fetal tissue research.

But I have to say I have to yield to you to explain what it is that you actually meant to say.

Dr. DONOVAN. Thank you.

Mrs. WATSON COLEMAN. Well, I wouldn't mind hearing that, if you could say it succinctly because I do have a number of questions.

Dr. DONOVAN. I am as succinct as I can be. You asked one of the most complex ethical questions: What do we do with the informa-

tion or products of medical research when we think the research itself is tainted?

Mrs. WATSON COLEMAN. That is not what I asked.

Dr. DONOVAN. That is what you asked, whether you realize it or not.

Mrs. WATSON COLEMAN. I simply asked—no, sir. No, I know what I asked. I asked, Do you think that it is better to discard the tissue that would result from an abortion that a woman made a decision to abort as opposed to a spontaneous abortion, an ectopic pregnancy aborted, do you think it is moral to throw it away, rather than use it for purposes of discovering cures, discovering treatments, et cetera? And if you can give me a "yes" or "no," I will take it. If not, I want to move on to the next question.

Dr. DONOVAN. Few questions, moral questions, are yes-or-no questions. That one certainly is not.

Mrs. WATSON COLEMAN. Thank you very much.

Professor Charo, we have heard about what has happened as a result of those videos that had been released. We know what has happened with regard to Daleiden and those videos. And we know that it has created harassment and fear and whatnot.

As a matter of fact, the dean of your school of medicine said that his faculty has been compared to Nazi war criminals because they use fetal tissue for research. Does it surprise you that the researchers have come under attack and that healthcare providers and doctors also were under attack? And could you give me a "yes" or "no"?

Ms. CHARO. It does not surprise me.

Mrs. WATSON COLEMAN. And what do you feel about that comparison?

Ms. CHARO. Thank you for giving me the opportunity to say something I have wanted very much to say. My family was personally touched by the Holocaust. I lost a grandparent in the camps. I grew up in a neighborhood where people wore tattoos on their arms that represented the years in the camps. These were people who were alive and were aware and were suffering for the years that they were in those camps. I am profoundly, profoundly distressed and, frankly, offended——

Mrs. WATSON COLEMAN. Thank you, Dr. Charo.

Ms. CHARO [continuing]. At the thought of comparing that to the experience of loss of an embryo or fetus.

Mrs. WATSON COLEMAN. Professor, I just thank you very much. Madam Chair, may I have 30 seconds?

Mrs. BLACKBURN. Yes.

Mrs. WATSON COLEMAN. Thank you very much. Because I simply wanted to say, Madam Chair, that we believe your efforts to compile this database of names are very dangerous. We believe that linking people to this investigation is very dangerous, and we think that the characterization of the unlawful sale of baby body parts is very dangerous, and we are disappointed that Republicans tabled our motion and that you would not answer Mr. Nadler's question when he asked you why you thought this was important. Thank you.

Mrs. BLACKBURN. The gentlelady's time has expired.

At this point, I recognize Ms. Hartzler for 5 minutes.

Mrs. HARTZLER. Thank you, Madam Chairman.

I would just say, based on the comments that were just made, that just a reminder that babies who are aborted are normally buried or cremated. It is not discarded. And so to follow this premise, you would be saying that to bury a loved one rather than donating to science is immoral. And I clearly, clearly reject that. We have to treat these babies with the dignity that they deserve, and I think the logic is flawed to say just because you don't donate a loved one to science, it is immoral.

But I want to talk a little bit about the consent. I was a former teacher for many years, working with teenagers, some that had a time in their life when they had an unexpected pregnancy, and these are very difficult issues. So, I would like to put up Exhibit E—excuse me, start with Exhibit D.

And so this question will start off with Ms. Cunningham. The Secretary of HHS issued the Belmont Report, which says that consent is valid only if voluntarily given. And that "inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable."

So—if you could put up Exhibit A–3, the consent form that is used in some of these clinics—I would like to ask you, in your view, does this form violate our Government's own guidance in its inducement to women considering abortion, especially with the promise and the statement in the very first opening of the consent form says: "Research using the blood from pregnant women and tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS"?

I will say I lost my mother last year with Alzheimer's. I am not aware that there is a cure out there. This was news to me. So, Ms. Cunningham, do you think that this consent form complies with HHS' mandate against inducement?

Ms. CUNNINGHAM. It would be interesting to know from the woman's perspective if this does induce her to sign the form, this idea of the promise of cures, which is a very powerful motivator.

The concern I have is that the standards that we have typically for fetal tissue donation are just absent here. And so in addition to the voluntariness, there is just the thoroughness of the consent seems to be missing in this form.

Mrs. HARTZLER. I would concur with the HHS informed consent checklist itself that is online. A couple of other requirements that are supposed to be of consensus, a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. I see no such statement in this exhibit. It also says that: "Research, Rights or Injury: An explanation of whom to contact for answer to pertinent questions about the research and research subjects' rights."

If I was a teenage girl in a crisis situation there being presented with this form, I don't see it there. Do you see it on the form?

Ms. CUNNINGHAM. I do not.

Mrs. HARTZLER. OK. Ms. Charo, last August, speaking about fetal tissue research while at a NARAL conference, you were quoted as saying, "Now remember, this is not about using an actual embryo or an actual fetus. This is leftover tissue after the fetus is long-dead."

Please put up Exhibit E. In this email, the tissue procurement manager of a tissue business described to a university researcher the immediacy of obtaining tissue from aborted fetuses. The manager wrote that after, quote, "the doctor determines the [abortion] is complete, the [procurement technician] is allowed to begin procurement. This takes a couple of minutes."

So, given these comments from the tissue procurer, how can you contend that tissue procurement occurs "after the fetus is long-dead"?

Ms. CHARO. I don't recall speaking at a NARAL conference last August, but there was a conference I spoke at considerably longer ago, speaking of length of time, and I believe that that comment was being made in the context of the cell lines, which really are from fetuses that were aborted a very, very long time ago. But I don't have a transcript of my own remarks with me. Thank you.

Mrs. HARTZLER. OK. Dr. Donovan, isn't the tissue harvested immediately after the cells—are they still alive, the cells are still alive?

Dr. DONOVAN. Absolutely. They want fresh cells.

Mrs. HARTZLER. OK, very good. I yield back. Thank you.

Mrs. BLACKBURN. The gentlelady yields back.

Mr. Nadler, you are recognized 5 minutes for questions.

Mr. NADLER. Thank you, Madam Chair.

Ms. Charo, I should first say that I find most of this discussion irrelevant, because it relates to the morality of abortion. Opinions differ, obviously, on the morality of abortion. I, for one, think abortions are perfectly moral, but that is not the question. Abortion is legal and, as a consequence, safe for women in this country.

The law already prohibits initiating a pregnancy for the purpose of donating tissue—a hypothetical concern, as we have never heard of this actually happening. The question before us is about fetal tissue research. But if the abortion was going to happen anyway—now, Dr. Harris pointed out and Dr. Donovan agreed that we all agree that fetal tissue research is valuable and the disagreement may be over the source. But if the abortion was going to happen anyway, even if you don't like that fact, how can it be immoral to save lives by use of fetal tissue from an abortion that would have happened anyway, tissue that would otherwise be thrown away? What makes the use to save lives instead of throwing it away immoral, Ms. Charo?

Ms. CHARO. There has been a great deal of conversation about the notion of complicity with an underlying act one considers to be immoral, and it is at this point, I think, it is helpful to take an example of an act that I think is universally understood to be immoral and not one that is debated, which is the case of abortion. If we talk about the murder of an adult, which we all consider to be immoral and is also a criminal act, so it is also not legal, there is no question that we use those tissues and organs from murder victims for organ transplantation, for tissue transplantation, and for organ and tissue research without in any sense feeling complicit. We don't encourage murder by virtue of using those tissues. We may not condone it, but we certainly don't view it as something that should be abandoned because we don't want any connection with an underlying act of which we disapprove.

So, I find the arguments about complicity to be unpersuasive.

Mr. NADLER. So, by the same logic, whether you think abortion is immoral or not, use of fetal tissue that would be there in any event for research purposes is no more moral or immoral than use of tissue from a murder victim?

Ms. CHARO. That was the reasoning of the panel that was led by Judge Adams for President Reagan, and that is a kind of reasoning that does not appear to have been affected by events in the last 30 or 40 years. Science changes, but that particular analysis seems to have persisted.

Mr. NADLER. Let me quote from Ms. Cunningham's testimony. And she said—and this is a sub-quote from a book by Robert George and Christopher Tollefsen—it is "morally impermissible to engage in any research for any purpose that involves the destruction of human beings at any stage of their lives, including the embryonic stage, or in any condition however weak or dependent."

Ms. Cunningham continues: "Those who are responsible for terminating the life of a fetus have failed to recognize this fundamental principle of human dignity and, thus, have no moral claim to be able to donate or assign the body, organs, or tissues of the fetus to others, regardless of the nobility of purpose." Dr. Donovan said something to the same effect.

In other words, Ms. Cunningham, Dr. Donovan, Mr. George who wrote the article, believe that they have a superior moral claim to that of the mother to make this decision. I find this incredibly arrogant. Because of their view of the morality of abortion, they would deprive the mother of her moral agency. Having decided to have an abortion, which is her right under the law—which some of us regard as moral and some people regard as immoral, but it is her decision under the law—they would deprive her, therefore, of the right to make a decision to use the fetal tissue that would otherwise be thrown out for morally good purposes to help save lives. And they would deprive the mother of this moral right because they have a superior moral right.

Would you comment on that, Ms. Charo?

Ms. CHARO. Yes, this was exactly the concern that was raised again and again by the Reagan panel, which did a fairly thorough report on a lot of these things. And they looked specifically at whether there is anybody else who is in a superior position to give consent. That could be scientists, it could be physicians. It could be that the material is used without any kind of consent at all and considered abandoned property. And in the end, they concluded that there was no one and no entity and no rule of law that had superior entitlement to make this decision than the woman herself.

Mr. NADLER. Thank you. I have one final question. Dr. Bucshon noted that it is legitimate to reexamine these issues. We had panels a couple of decades ago. We can reexamine the issues. He is right, of course, on that. We can always reexamine an issue. And he said, What are we afraid of?

Here is what we are afraid of: "We also know that an employee at one of the entities that the Chair has subpoenaed, someone who is also identified in connection with the deceptively edited and false videos, has been the victim of a death threat posted online, suggesting that he or she should be hung by the neck using piano wire

and propped up on the law in the front of"—on the lawn, I assume he meant—"in the front of the building with a note attached," unquote. That is what we are afraid of, that this kind of proceeding that we are doing, with the kinds of obnoxious and illegal and—frankly, subpoenas I think designed to endanger the lives of people who engage in abortions, that is the danger.

Ms. Charo, would you comment on that? And that is my last question.

Ms. CHARO. It is a documented danger. We also saw, as was noted earlier on, the deaths in Colorado immediately following some of these tapes being released. I can say from personal experience not related to this topic but other topics I have written on, I have also received threatening calls, and it is incredibly disturbing and it is a way to intimidate and chill research in the United States.

Mr. NADLER. And make this committee complicit in further acts of violence, if they occur. Thank you very much.

Mrs. BLACKBURN. The gentleman's time has expired.

Mrs. Love for 5 minutes.

Mrs. LOVE. Thank you.

Across the United States, current Federal law prohibits minors under the age of 18 from serving in the military, entering into financially binding contracts, purchasing nicotine, being tried as an adult, getting married, or voting. We have a number of laws in place that protect our minors. This includes prohibiting minors to go into certain movies without a guardian or a parent being around. And all of this is to protect that minor because their brains are not fully developed and they lack the ability to fully comprehend long-term repercussions of their decisions.

So, my question, Ms. Cunningham: Do you think that ethical guidelines should be in place to protect a minor when they are giving consent to a clinic to perform an abortion, and what kind of guidelines do you think should be in place?

Ms. CUNNINGHAM. Are you thinking about the abortion procedure itself or the specific issue of consent to donate?

Mrs. LOVE. I am not talking about tissue donation. I am talking about when they are going in and actually giving consent to even have an abortion performed.

Ms. CUNNINGHAM. Well, I think, first of all, there should be great care exercised because, as the United Kingdom Human Fetal Tissue Authority noted, that the time of deciding about abortion is a very emotionally stressful time for a woman. And I have been in a number of conversations with physicians involving informed consent, and it is really helpful to have the second person there taking notes and really paying attention to what is said. My own husband didn't remember what the oncologist said to him, but I took notes and I was able to help him go through the informed consent process.

So, I think great care would need to be taken in any kind of informed consent proceeding, but especially with a minor.

Mrs. LOVE. OK. Mr. Donovan, with all of this being said, do you think it is important for us to have different consent forms for minors versus adults?

Dr. DONOVAN. Well, in fact, in medical research, children cannot give consent. They are allowed to give what we refer to as assent, but they also require the permission of the parent involved as well.

Mrs. LOVE. OK. Given what we know today with current laws governing consent from minors, what do you think would be an appropriate age for someone to get an adult consent form as opposed to a minor that is given consent for an abortion?

Dr. DONOVAN. Well, at least in research, under the law, at 18 they can start signing a consent form, although human development specialists suggest that maybe sometime around the age of 24, teenagers actually do grow up.

Mrs. LOVE. I want to actually concentrate a little bit now on the tissue donation. I have a 14-year-old child. I am not a physician. My expertise is in real life, in the real-life aspect. I have this 14-year-old, who is a straight-A student and makes decisions, great decisions, generally, most of the time. And under normal circumstances, I actually asked her to look at this exhibit and try and figure out whether she can fill that form out. My very smart child kept coming back to me asking for explanation, clarification. And those are normal circumstances.

So, let me ask you this question: What kind of emotional duress do you think a minor is under in anticipation of an abortion procedure? Just your thoughts. I mean I can imagine what I would go through. Either one. Ms. Cunningham, this is a great question for you. What kind of duress do you think a minor would be under before having to go under, having to have a procedure, an invasive procedure like an abortion?

Ms. CUNNINGHAM. Well, having raised a daughter who has survived adolescence but who has been with her in physician consultations, there is stress over dealing with a sprained arm. There is great stress over going through an x-ray, after she fainted. There must be even greater stress in an event that she may be wishing to conceal from others.

Mrs. LOVE. OK. So, imagine that 14-year-old going into a clinic to undergo a very invasive procedure without someone there that she trusts to walk her through, to make sure that she is not being taken advantage of, to make sure that she is making the right decision. How can anyone be sure that that minor, under difficult circumstances, fully understands the long-term repercussions behind their decision when the current law wouldn't even allow that minor to get behind the wheel of a vehicle?

Dr. DONOVAN. You are pointing out a real discrepancy between the way we deal with the teenagers in our country. I wouldn't be able to take that child and do a procedure on them without the mother or father being there and giving their consent as well. If I did, that would be assault and battery.

Mrs. LOVE. Thank you.

Mrs. BLACKBURN. The gentlelady yields back. Mr. Duffy, you are recognized for 5 minutes.

Mr. DUFFY. Thank you, Madam Chair, and welcome, panel.

I want to be clear, Ms. Charo, on your testimony, and that is that there is, I think you said there is a compelling public interest in research on fetal tissue. Is that right?

Ms. CHARO. Yes, I said that.

Mr. DUFFY. And this is about saving lives, correct?

Ms. CHARO. That is what I said.

Mr. DUFFY. OK, now I think I heard you correctly when the Chair asked you in the first round of questions about whether there is any ethical violations in regard to using fetal tissue for taste tests, cosmetics, or human and animal DNA testing. And I think Mr. Donovan and Ms. Cunningham expressed concern, but you did not.

So, could you explain to me the compelling public interest and the lifesaving research that takes place when we use fetal tissue for taste tests and cosmetics?

Ms. CHARO. First, I am referring to the full range of uses, which includes all of the basic science research that you hear about——

Mr. DUFFY. No, no, no. I am reclaiming my time, because this was very specific.

Ms. CHARO. No, actually, the question was whether I thought there was a compelling public interest.

Mr. DUFFY. I am reclaiming my time.

Ms. CHARO. And I am talking about the full range.

Mr. DUFFY. Ms. Charo, the question came specifically from the Chair about taste tests and cosmetics and human and animal DNA testing. And you didn't express any concern.

So, do you have a compelling public interest that saves lives in regard to taste tests and cosmetic research using the fetal tissue? "Yes" or "no"?

Ms. CHARO. I am going to take a page from you and say I can't say "yes" or "no," because that is not actually what I said. I did not express no concern. I said those are probably more frivolous, but they are among the many uses for tissue.

Mr. DUFFY. So, let me ask you this: Do you think there is a compelling public interest in saving lives if we use fetal tissue for taste tests and cosmetics?

Ms. CHARO. Believe it or not, for taste tests there might be because actually the loss of taste neurologically can actually lead to devastating problems.

Mr. DUFFY. And how about cosmetics?

Ms. CHARO. It depends on which cosmetics you are talking about. A lot of those skin grafts are considered aesthetic, but they are also very, very helpful.

Mr. DUFFY. Is there anything, any research that you think is inappropriate using fetal tissue?

Ms. CHARO. Well, using any tissue, fetal or adult, I find the cosmetic uses in Hollywood sometimes to be so frivolous, I would be perfectly happy to see us abandon them.

Mr. DUFFY. I want to be clear because it seems that you are here advocating, you are advocating on behalf of fetal tissue research and stem cells. You have also consulted with companies that are involved in those activities. And in the CV you provided in preparation for your testimony, in 2002 you were on the Scientific Advisory Board of WiCell. And in their Web site it shows that it does stem cell research. In 2012, you were a consultant to Cleveland BioLabs. And in their SEC filings, Cleveland BioLabs says it uses proprietary stem cell lines in its products. And in 2006, you were a consultant to Stem Cells, Inc. That firm's Web site says that it uses

"human neural stem cells" in medicine. A leading university told the panel that it "receives a proprietary stem cell line derived from fetal tissue that was supplied by Stem Cell, Inc."

So, you do have a vested financial interest in the boards that you serve on the research of fetal tissue. Correct?

Ms. CHARO. I receive no funding from WiCell. I did receive consulting funding from Cleveland and Stem Cells, Inc. Those were not embryonic stem cells, by the way, that we were talking about.

Mr. DUFFY. So, you do have a financial interest in——

Ms. CHARO. Not at present, no.

Mr. DUFFY. But you have in the past?

Ms. CHARO. I have.

Mr. DUFFY. OK.

Ms. CHARO. And by the way, every dollar of that was donated. You can look at my IRS tax returns.

Mr. DUFFY. OK. So, I want to go to another few issues. So, let us say—and if we could go to Exhibit A–1—if we have someone who works for a tissue procurement business, and they are corresponding with an abortion clinic technician and they are providing a wish list of items that they are going to want to purchase, things like a liver, thymus, skin to be shipped by FedEx overnight, whether to Harvard or UMass. So, you have a wish list, a shopping list being sent from the tissue provider to the abortion technician.

And if we could also go to Exhibit A–2, here is a procurement compensation schedule. So, we see the technician gets paid per specimen. And the more specimens you provide, the more money you make. And just a side note: I thought that there was no profit motive here. I don't think that per specimen the cost goes up, but the more you provide, the more money you make above your hourly wage, Exhibit 2–A.

And then if you go to Exhibit A–3, you have a consent form that the technician brings out to the mom to garner consent for the abortion. I would just note that if the panel would look at their Exhibit A–3, anywhere in there does it say that the technician has a financial interest where they obtained $35 per specimen up to 10 specimens and $45 per specimen for those from 11 to 20? Does a financial incentive, is that shown in Exhibit A–2—or I am sorry A–3, if you look at that quickly?

Dr. DONOVAN. No, it is not there.

Mr. DUFFY. OK. Does that concern you, that we have the technician who is receiving the shopping list from the business and it is also the person that is going to go in and obtain consent from the mom and the financial component to it? Mr. Donovan, does that give you any pause or concern ethically?

Dr. DONOVAN. Well, I think that you have correctly shown that this would never pass muster for an IRB.

Mr. DUFFY. Ms. Cunningham?

Ms. CUNNINGHAM. Yes, it has ethical problems.

Mrs. BLACKBURN. The gentleman's time has expired.

Mr. DUFFY. My time has expired. I am getting gaveled down. I yield back.

Mrs. BLACKBURN. I thank the gentleman. I want to thank our first panel for being with us today.

We are ready to move to our second panel. And as the first panel departs, I want to provide unanimous consent, so ordered, to Mrs. Black for her request to enter the Department of Health and Human Services' Office of Inspector General Report on Tissue Donation into the record. So ordered.

[The information appears at the conclusion of the hearing.]

As our first panel leaves, we will introduce the second panel, as they take their places, Dr. Lee, Dr. Schmainda, and Dr. Goldstein.

And I would like to introduce the members of this panel, Dr. Patrick Lee is the John N. and Jamie D. McAleer Professor of Bioethics and the Director of the Center for Bioethics at Franciscan University of Steubenville. Dr. Kathleen M. Schmainda is Professor of Radiology and Professor of Biophysics at the Center for Imaging Research at the Medical College of Wisconsin. And Dr. Lawrence Goldstein is Distinguished Professor, Department of Cellular and Molecular Medicine, Department of Neurosciences at the University of California San Diego School of Medicine.

You are aware that the Select Investigative Panel is holding an investigative hearing and will take your testimony under oath. Do you have any objection to testifying under oath?

The Chair then advises you that under the rules of the House Committee on Energy and Commerce, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today?

If you will stand to be sworn in.

[Witnesses sworn.]

Mrs. BLACKBURN. Thank you. You may be seated.

You will each have 8 minutes for your opening statement. Dr. Lee, you may proceed.

STATEMENTS OF PATRICK LEE, PH.D., JOHN N. AND JAMIE D. MCALEER PROFESSOR OF BIOETHICS AND DIRECTOR, CENTER FOR BIOETHICS, FRANCISCAN UNIVERSITY OF STEUBENVILLE; KATHLEEN M. SCHMAINDA, PH.D., PROFESSOR OF RADIOLOGY AND BIOPHYSICS AND VICE CHAIR, RESEARCH DEPARTMENT OF RADIOLOGY, MEDICAL COLLEGE OF WISCONSIN; AND LAWRENCE GOLDSTEIN, PH.D., DISTINGUISHED PROFESSOR, DEPARTMENT OF CELLULAR AND MOLECULAR MEDICINE, DEPARTMENT OF NEUROSCIENCES, AND DIRECTOR, UNIVERSITY OF CALIFORNIA, SAN DIEGO, SCHOOL OF MEDICINE

STATEMENT OF PATRICK LEE

Dr. LEE. Thank you, Chairman.

Mrs. BLACKBURN. Microphone, please.

Dr. LEE. Thank you, Madam Chairman Blackburn, and thank you, distinguished members of the committee. And thank you for this opportunity for speaking on bioethics and fetal tissue.

My name is Patrick Lee. I am a professor of bioethics at Franciscan University of Steubenville, and I have submitted my written testimony. I will just give a brief summary of some of the arguments there.

In Roe v. Wade, Justice Blackmun claimed that the Court would not settle the question of whether the fetus is a human being or

not. And yet, as a practical matter, the Court denied two human fetuses the equal protection of the law and so treated them as, in fact, outside the class of human beings.

In fact, however, as the standard text of embryology, developmental biology, and genetics assert, a human embryo or fetus from conception on is a distinct, whole human individual. The evidence for this is quite clear. We know that a human embryo or fetus is a human being, a human organism, in basically the same way we know the 6-week-old infant is a human organism. Looking at a 6-week-old infant, we can see that, first, she is a distinct being, not a part of a larger organism. She is a complete being, although at an immature level of development, since even though she cannot now perform many of the actions that are typical of human beings, she is growing. She is actively developing herself to the point where she will do so.

In a similar way, it is clear that a human embryo or a fetus is a distinct being, since she grows in her own distinct direction. She is, obviously, human, since she has the genetic structure in her cells that is characteristic of humans. And she is a whole human being, as opposed to something that is functionally apart, such as a human cell or human tissue. For, unlike a cell or a human tissue, she has within her structure, within her genetic and epigenetic structure, all of the internal resources needed to actively develop herself to the mature stage of a human being. This shows that she already is a whole human organism, only at the earliest stage of development.

So, the same kind of facts that show a 6-week-old infant is a human being also show that a human embryo or fetus is a human being, a human organism. And since what we are are human organisms, bodily beings, it follows that she is the same kind of being as you or me, only at an earlier stage of her lifecycle. Just as you and I once were adolescents, and before that children, and before that infants, so we once were fetuses and we once were embryos.

Moreover, since what makes you and me intrinsically valuable as subjects of rights is what we are, our fundamental nature, it is wrong intentionally to kill us and it would have been wrong to kill us when we were embryos or fetuses. All human beings, unborn as well as born, no matter at what age or size, are created equal and are endowed by their creator with fundamental, unalienable rights. Therefore, it is gravely unjust to provide protection of the law to born human beings but to deny it to unborn human beings.

Since what is killed in abortion is a human being, the further act of governmentally funding and endorsing abortion providers is an additional injustice. By subsidizing abortion providers, the Government, unlike the Court in Roe v. Wade, cannot even make a pretense of being neutral on the question of whether what is killed in abortion is a human being. To subsidize and encourage the killing of human fetuses is to presuppose in that act that what is killed in abortion is not a human being.

Furthermore, the donation of organs after death in general requires authoritative consent from the person who dies or, if a minor, from her parent. In the case of fetal organs or tissues, parental consent would be required. This seems permissible in the case of spontaneous miscarriages or ectopic pregnancies. However,

that is not the case with relying on the consent of the parent of an elective abortion. Parental authority over children is based on the special connection of parents to their children, a connection that creates a special responsibility of parents to their children, responsibility to care for them and to be devoted to their well-being. Grave abuses of that relationship or actions indicating that a parent no longer has the child's interest at heart cause the parent to lose that parental authority. But the choice to have the child killed, even if done in confusion and with mitigated responsibility, is incompatible with a willingness to act in the true interest of the child. Thus, the practice of allowing or encouraging the use of fetal tissue obtained from elective abortions, relying, as it does, on the mother's consent, treats the bodily parts of the fetus as if they were parts of the woman's body. The practice makes no sense, unless the fetus is assumed to be something other than a human being.

Therefore, governmental funding of abortion providers and the use of fetal tissue from elective abortions involve profound dehumanization of unborn human beings and are grave injustices.

Thank you.

[The prepared statement of Dr. Lee follows:]

Testimony of
Patrick Lee, Ph.D.
John N. and Jamie D. McAleer Professor of Bioethics
Franciscan University of Steubenville
Before the Select Investigative Panel of the Committee on Energy and Commerce, "Bioethics and Fetal Tissue"
March 2, 2016

Chairman Blackburn, and distinguished members of the Committee on Energy and Commerce, my name is Patrick Lee. I am the John N. and Jamie D. McAleer Professor of Bioethics, and the Director of the Center for Bioethics, at the Franciscan University of Steubenville. Thank you for this opportunity to speak to you about bioethics and fetal tissue.

I will argue that it is unjust for the government to fund or encourage elective abortions. To do so is not only to deny a class of human beings—unborn human beings—equal protection of the law, it significantly assists in those killings. Second, it is a further injustice for the government to allow or encourage the use of fetal tissues procured from elective abortions. And third, allowing the use of fetal tissue obtained from abortions on the ground of the mother's consent is a further injustice and depersonalization of unborn human beings. Women who choose to have direct abortions by that act forfeit the moral standing needed for being a proxy decision-maker in regard to the disposition of their baby's remains.

There are both moral and legal questions concerning abortion. I will address legal issues—not what actually is the law, but what the law should be, or what laws concerning the specific issues addressed here would be, as far as I can see, in accord with justice.

A central question for all of these issues is: What type of being is killed in abortion? I will argue that in fact what is killed in abortion is a human being, a person, deserving of our respect and of protection of the law. Every human being deserves equal protection of the law, and so if human embryos and fetuses are in fact human beings—some of the evidence for which I will indicate in a moment—then it is gravely unjust to provide protection of the law to born human beings, but deny it to unborn human beings. *A fortiori,* the political community should not encourage and assist the killing of unborn human beings by funding abortion providers.

So, what does the evidence indicate regarding what is killed in abortion? No one denies that *something* is killed in abortion. What type of being is it?

This question, in turn, subdivides into two. First, is the human embryo or fetus a human being? That is, is the human embryo or fetus a member of the human species, a human individual? Second, if what is killed is a human being, is it also a person, since some admit that the human embryo or fetus is a human being, but deny that he or she is a person, a being with basic rights. (Here I am using the term "person" in its everyday sense rather than raising the question of what the Constitution meant by it.)

The standard scientific texts on this issue—in embryology, developmental biology, and genetics—explicitly affirm that a human being at the earliest stage of development comes to be at fertilization. Here are three of many, *many* examples:

> **"Human life begins at fertilization, the process during which a male gamete or sperm unites with a female gamete or oocyte (ovum) to form a single cell called a zygote. This highly specialized, totipotent cell marked the beginning of each of us as a unique individual." "A zygote is the beginning of a new**

human being (i.e., an embryo)." Keith L. Moore, The Developing Human: Clinically Oriented Embryology, 7th edition. Philadelphia, PA: Saunders, 2003. pp. 16, 2.

"Fertilization is the process by which male and female haploid gametes (sperm and egg) unite to produce a genetically distinct individual." Signorelli et al., Kinases, phosphatases and proteases during sperm capacitation, CELL TISSUE RES. 349(3):765 (Mar. 20, 2012)

"Although life is a continuous process, fertilization (which, incidentally, is not a 'moment') is a critical landmark because, under ordinary circumstances, *a new, genetically distinct human organism is formed* when the chromosomes of the male and female pronuclei blend in the oocyte" (emphasis added; Ronan O'Rahilly and Fabiola Mueller, *Human Embryology and Teratology*, 3rd edition. New York: John Wiley & Sons, 2000, p. 8). (Many other examples could be cited, some of which may be found here: http://clinicquotes.com/list-of-quotes-from-medical-textbooksscientists-proving-life-begins-at-conception/)

As long as they are clear that the question is about the coming to be of a distinct human organism—and not about the philosophical question of personhood—the authorities are in agreement. And they agree because the underlying science is clear. At fertilization a sperm unites with an ovum, each of them ceases to be, and a new entity is generated, the embryo, initially a single totipotent cell, called the zygote. (Hence it makes no sense to say that a sperm or an ovum becomes a mature human, or that a sperm or an ovum has the potential to become a mature human: Ingredients do not become what

they enter into, whereas an immature human being — an embryo, fetus, or infant — does become an adult human being simply by maturing.) It is obvious that the human embryo is a *distinct* entity, not a part of the mother or a part of the father. For unlike body cells, tissues, or organs, the embryo does not function as part of its mother. Moreover, the cells of the embryo or fetus have a genetic structure distinct from that of the mother or the father.

The one-cell embryo (zygote) develops by dividing into two cells, then four, then eight and so on (though some divisions are asynchronous and so there is usually a three-cell stage for example). While these divisions occur, all of the cells continue to be enclosed within a thin membrane called the zona pellucida, which is inherited from the ovum.

Are these merely a bundle of disparate cells? The evidence shows, on the contrary, that together they make up a single organism. These cells inter-communicate and function together as parts of a whole in a regular and predictable manner. As a result, they perform an ordered, differentiated growth and constitute a stable body. For example, as the embryo travels down the uterine tube into the uterus during the first four or five days, the different cells begin differential gene expression (modifications of different parts of the DNA within the cells' nuclei in order to generate different types of new cells that can function in different ways), with the result that different parts of the embryo are suited to different functions.

On day three or four, at the transition from the eight-cell stage to the 16-cell stage, the embryo differentiates into trophoblastic cells (precursors of the placenta) on the one hand, and inner cell mass cells (precursors of the permanent part of the embryo and

fetus), on the other hand. This is the first overt functional differentiation that occurs, but the cells have been preparing for this differentiation since day one.

So from the zygote stage onward the cells are functioning as parts of a whole, and are internally coordinated toward the next step in a developmental trajectory that eventually involves the development of a body plan and distinct organs. This is a new and distinct multi-cellular organism. It is developing itself in a predictable direction. Obviously it is also *human* since its cells have the genetic structure characteristic of humans.

Is this a *whole* human organism? This question is important because human tissue and human cells alone are not whole human organisms — for example, an isolated skin cell or a heart before it's implanted into a recipient. Each of these is human but neither is a whole organism.

The evidence indicating that the human embryo is a whole human being is that it has within itself all of the internal resources and the active disposition to develop itself to the mature stage of a human being. The direction of its growth is internally coordinated — what it receives from outside itself is only a suitable environment and nutrition. The organizational information for its growth comes from within.

Moreover, at no stage after fertilization does there occur a fundamental change in its direction of growth. None of the changes that occur to this being after the sperm-egg fusion— as long as this being stays alive — qualify as producing a fundamental change in its interiorly directed growth, so as to involve the coming to be of a new organism. Rather, everything that happens after fertilization either assists or retards its interiorly directed self-development.

Thus, given its genetic constitution and epigenetic structure, all this organism needs to develop to the mature stage is what human beings at any stage need, namely, a suitable environment, nutrition, and the absence of injury or disease. So it is a whole human organism—a new human individual—at the earliest stage of his or her development.

Sometimes it is objected that if we say human embryos are human beings, on the grounds that they have the potential to become mature humans, the same will have to be said of sperm and ova. This objection is untenable. The human embryo is radically unlike the sperm and ova, the sex cells. The sex cells are not *whole* or *complete* organisms. They are not only genetically but also functionally identifiable as parts of the male or female potential parents. They clearly are destined either to combine with an ovum or sperm or die. Even when they succeed in causing fertilization, they do not survive; rather, their genetic material enters into the composition of a distinct, new organism.

Nor are human embryos comparable to somatic cells (such as skin cells or muscle cells), though some have tried to argue that they are. Like sex cells, a somatic cell is functionally only a part of a larger organism. The human embryo, by contrast, possesses from the beginning internally orchestrates its growth toward its own survival and development rather than that of a larger system.

So, a human embryo (or fetus) is not something distinct from a human being; he or she is not an individual of any non-human or intermediate species. Rather, an embryo (and fetus) is a human being at an early stage of development—the embryonic (or fetal) stage. In abortion what is killed is a human being, a whole living member of the species

homo sapiens, the same *kind* of entity as you or I, only at an earlier stage of his or her development.

However, some grant that a human embryo or fetus is a human organism. but argue that she is not a person, she is not a bearer of rights. In order to be a person, some object, an entity must have some characteristic in addition to being a human being—it is not enough, on their view, to be identical to a being that is clearly a person at a later time. They might hold, for example, that to be a person a being must have self-awareness or self-conscious desires—in the sense of an the immediately exercisable capacity for those acts. (It is worth noting that every human being, including human embryos or fetuses, has a radical capacity (or root capacity) for self-consciousness, rational acts, and so forth; even though they cannot now perform such acts, they have the capacity to develop themselves to the point where they will perform them—just as, even though I cannot now read Chinese, I have the root capacity to do so since I can acquire the immediately exercisable capacity to do so by study.)

If this position were right—that is, if one needed self-consciousness, or an immediately exercisable capacity for self-consciousness, in order to be a person—then it would be hard to see how a human being in a temporary coma would qualify as a person. A human being may be in a coma for several weeks—during that time she is very much like an embryo or fetus. She cannot right then, that is, while she is in a coma, engage in self-conscious acts, or any type of higher mental acts. But she remains a person. I suggest that the clearest reason why a human being in a coma is still a bearer of rights is that she is the same kind of being as you and me; she is an individual with the internal resources to develop herself to the point where she will have self-consciousness and

shape her life by deliberate choices. She has basic rights because she remains a human being.

Someone might also object that the individual who is in a coma is different from a human embryo or fetus. The individual in a coma *did* have consciousness and self-conscious desires in his life in the past. And this being is a person, because of that past self-consciousness and desires.

But suppose I were in a coma, as a result, say, of a brain tumor that affected only a certain portion of the cerebral cortex, and we knew that after life-saving surgery I would regain consciousness in the future, but not any of the same consciousness, or any of the same memories or skills I had in the past. Suppose I would only gradually regain full consciousness and I would have to learn everything again—how to walk, talk, and so on. Would it be right to kill me then? Of course not—but that would not be because of my past consciousness or self-awareness, since all of that consciousness, all those memories, mental skills, and so forth, are gone forever. In this situation, it would be wrong to kill me because by killing me you would be depriving me of my whole future as a rational being, a being that, although not now conscious or self-aware, has a nature orienting him toward the stage where he will do all the things that distinguish human beings from other living beings that do not possess basic rights. What makes it wrong to kill me in such a situation is not that one would be killing something that has an immediately exercisable capacity for consciousness—it is enough if I am identical to the thing that eventually will have rational consciousness in order to have a right to life.

So, to be a bearer of basic rights, it is enough if an entity is constituted in such a way that she has an active disposition to develop herself to acquiring rational

consciousness. But the hypothetical scenario I have just referred to is in relevant respects similar to the position of human embryos and fetuses. Human embryos and fetuses are human beings—animal organisms with the active disposition to a rational mode of life. Thus, just as it would be wrong to kill me if I were in a coma, while I was still unconscious but slowly developing to the point where I would be conscious, so it is wrong to kill human embryos or fetuses because they are human beings, individuals actively developing themselves to the stage of a rational mode of life.

Further, being a whole human being (whether immature or not) is an either/or matter—a thing either is or is not a whole human being. But all of the acquired qualities that could be proposed as criteria for personhood come in varying and continuous degrees: there is, for example, an infinite number of degrees of self-consciousness or the possession of self-conscious desires. So if human beings were bearers of rights only because of such qualities, and not in virtue of the kind of being they are, then, since such qualities come in varying degrees, no account could be given of why basic rights are not possessed by human beings in varying degrees.

The proposition that all human beings are created equal would be relegated to the status of a superstition. For example, if developed self-consciousness bestowed rights, then, since some people are more self-conscious than others (that is, have developed that capacity to a greater extent than others), some people would be greater in dignity than others, and the rights of the superiors would trump those of the inferiors. This conclusion would follow no matter which of the acquired qualities generally proposed as qualifying some human beings (or human beings at some stages) for full respect were selected. But in truth are persons do possess an equal and inherent fundamental dignity; it is wrong to

relegate some persons to an inferior position on the grounds of an alleged inferior worth. Indeed, our nation is rightly dedicated to the proposition that all human beings are created equal. Human beings are not equal in respect to inessential attributes. But they are equal with respect to their common human nature. Basing rights on inessential attributes logically entails the denial of equal fundamental rights. Thus, equal fundamental rights are best explained by the position that such rights are based on our human nature, and all human beings are equal precisely in their human nature.

So, 1.) the human embryo, from fertilization onward, is a human being; 2.) the human embryo or fetus and has fundamental rights, simply in virtue of being a human being. So, it is unjust intentionally to kill, or discard, an unborn human being, as occurs in abortion. It is wrong to kill you or me today because of the fundamental kind of beings that we are, and it would have been wrong to kill us when we were adolescents, wrong to kill us when we were children, but it also would have been wrong to kill us when we were fetuses or embryos.

Unborn human beings differ from born human beings in many ways—for example, in size, ways of obtaining oxygen and nutrition, and level of development. But they also are alike in many ways. Most important, each is a human being, only at different stages of development. I submit that it is the fundamental likeness, or sameness, rather than the difference, that is morally significant.

Since what makes you and me intrinsically valuable as subjects of rights is what we are, it follows that you and I are intrinsically valuable from the moment we come to be, and do not cease to have intrinsic value as persons until we cease to be. The

Declaration of Independence has it right: All human beings—not just those whose lives are convenient or non-burdensome to us—possess equal and inherent dignity and rights. No class of human beings can with justice enslave, use, experiment on, or deliberately kill, other innocent human beings for their own purposes.

This was the principle at stake in the 19th century with the issue of slavery and is also at stake with the civil rights movement in the 20th and 21st centuries. It is the same principle that is at stake in the debates concerning unborn human life. Just as all human beings, no matter what the color of their skin, deserve equal protection of the law, in the same way, all human beings, no matter what their age or degree of development, deserve that protection.

In *Roe v Wade* Justice Blackmun famously—or infamously—claimed that the Court would not settle the question of whether the fetus is a human being or not. And yet as a *practical* matter the Court could not refrain from either treating these human fetuses as human beings or treating them as subhuman objects that can be killed or disposed of. The political community will either include a class of entities within the scope of the protection of the law or it will not. If it does, then at least to that extent it treats them as persons; if it does not, it treats them as non-persons. Since it is a practical matter it cannot leave the issue undecided.

Moreover, the further act of governmentally funding and endorsing abortion providers is an additional injustice (and one not clearly authorized by Roe v Wade or cases stemming from it). *Roe* attempted to avoid the question of whether what is killed in abortion is a human being. But by subsidizing abortion providers the government cannot

even make a pretense of being neutral on the abortion issue—to subsidize and encourage the killing of human fetuses is to presuppose that what is killed is *not* a human being.

Finally, there is a serious problem concerning the woman's consent regarding the use of tissues and organs from the abortion procedure. How can her consent have ethical or legal significance, given her previous choice to abort?

The donation of organs after death requires authoritative consent from the person who died or, if a minor, from her parent (or legal guardian). In the case of fetal organs or tissues parental consent is required. This seems permissible in the case of spontaneous abortions (miscarriages) or ectopic pregnancies. However, there is clearly a problem in the case of elective abortion. Parental authority over children is based on the close union or connection of parents to their children that creates a special responsibility of parents to their children, a responsibility to care for them and be devoted to their survival and well-being, and to rear them to maturity. Grave abuses of that relationship, or actions indicating that a parent no longer has the child's interest at heart, cause the parent to lose that parental authority. That is, parental authority is contingent on the parent's willingness to have the child's interest in heart. A parent's failure to care for a child in a very grave way, or a parent's grave harm or abuse of a child, results in the loss of parental authority and of the parent's right to make decisions for that child. But the choice to have the child killed—even if done in confusion and mitigated responsibility—is incompatible with a willingness to act in the true interests of the child. Thus, the practice of allowing or encouraging the use of fetal tissue obtained from elective abortions, relying as it does on the mother's consent, treats the bodily parts of the fetus as if they were parts of the woman's body. The practice makes no sense unless the fetus is

assumed to be a sub-personal object, related to the mother as a possibly bothersome part of her, rather than as—which in truth she is—a distinct human individual.

I submit that governmental funding of abortion providers, and the use of fetal tissue from elective abortions, involve flagrant denials of the humanity of the fetus and are grave injustices.

Mrs. BLACKBURN. Thank you, Dr. Lee.
Dr. Schmainda, you are recognized, 8 minutes.

STATEMENT OF KATHLEEN M. SCHMAINDA

Dr. SCHMAINDA. Distinguished Chair Blackburn and honored members of the panel, thank you for the opportunity to offer my testimony in defense of infant lives and, specifically, in opposition to research using fetal tissue derived from induced abortions.

As background, I was trained in the disciplines of engineering and medicine, receiving a Ph.D. degree in medical engineering jointly awarded by Harvard University and Massachusetts Institute of Technology. I am currently a Professor of Radiology and Biophysics, serving as Vice Chair of Radiology Research at the Medical College of Wisconsin. I have participated in medical research for nearly 25 years. I have served on grant review panels for the National Institutes of Health for nearly 15 years, including a 4-year term on the developmental therapeutics study section.

I serve on national advisory committees for clinical trials and have founded two start-up companies. Most importantly, I am a wife and a mother.

The views expressed are my own and do not represent the official views of the Medical College of Wisconsin.

I am firmly opposed to research using fetal or embryonic tissue from induced abortions or procedures such as in vitro fertilization. I am compelled to create awareness amongst the community and my colleagues as to why the use of such tissue is both unethical and unnecessary.

Let me begin by defining terms. The terms "embryo," "fetus," "baby," or "infant" each refer to different stages in the continuum of the developing child. When cells are extracted during the earliest stages, these are typically human embryonic stem cells, which are obtained by destruction of the human embryo. When I speak of fetal tissue research, I am referring to cells, tissues, or organs that are harvested from an aborted fetus. While this is the focus of my testimony, my arguments apply to the continuum of the developing child.

Proponents of research using fetal tissue make several claims. The first claim is that, without fetal tissue, many of the life-saving treatments we have today would not have been possible. Second, it is argued that without continued access to fetal tissue, we are preventing the discovery of new therapies. And third, it is alleged that proper ethical guidelines are already in place to avoid the connection between abortion and fetal tissue research. I will speak to each of these claims.

First, it needs to be made clear that there are no current medical treatments today that have required use of fetal tissues for their discovery or development. While the often-cited polio vaccine was developed using fetal tissue cells, the developers later testified that initial studies were also successful using cells that were not of fetal origin. Though most vaccines today offer ethical alternatives, not all are available in the U.S. and some, such as chicken pox and Hepatitis A, currently do not have ethical alternatives. Yet, let me make it clear there has never been a scientific reason requiring fetal cell lines for vaccine development.

Testimony given to the FDA dated May 16, 2001, underscores this point. The developer of two common fetal cell lines, HEK 293, human embryonic kidney, and Per C6, isolated retina from a fetus, stated that his motivation for developing these cell lines from aborted fetuses was simply to see if it could be done in comparison to what had already been done with animal cells. Since then, use of these cell lines has become widespread and the manufacturers have no motivation to invest the time or money necessary to produce ethical replacements.

Due to lack of transparency, scientists can unknowingly become entrenched in using these cell lines. For example, the HEK 293 cell line is often offered as part of a standard kit available from biotechnology companies and branded under various names. Only upon specific request are alternatives provided. This lack of transparency is devastating for scientists who have ethical objections to use of this tissue and amounts to moral coercion.

Second, I refute the claim that, without continued access to fetal tissue, the discovery of new therapies will be prevented. The evidence is overwhelming to the contrary. For example, insulin for diabetes is produced in bacteria. Chinese hamster ovary cells have been used for the development of Herceptin for breast cancer and TPA for heart attack and stroke. There are more 70 successful treatments developed using adult stem cell sources. Over one million bone marrow transplants, which are essentially adult stem cell transplants, have been performed to date.

Still, some continue to claim that fetal cells unequivocally provide the best option because they divide rapidly and adapt to new environments easily. But, alternative tissue and cells sources are available for research without ethical concerns and are demonstrating more versatility than originally thought. Examples include stem cells from bone marrow, circulating blood, umbilical cord, and amniotic fluid, as well as induced pluripotent stem cells and even neural stem cells from cadavers. Adult stem cells have already been used for the development of new treatments, have been proven in clinical trials, and resulted in the formation of new companies, which have successfully brought to market treatments that are routinely benefitting patients today.

There is still no viable medical use for embryonic stem cells. Yet, the argument continues that keeping this avenue of research open may someday offer the only hope for a child with a devastating disease or a person with spinal cord injury.

In 1997, in The New York Times, it was reported the Nation's first transplant of fetal tissue into a person with spinal cord injury. The study required five to eight fetal spinal cords for each adult recipient but showed no significant therapeutic benefit. Many more studies followed with none showing significant therapeutic benefit, yet with each continuing to claim great promise. The promise without benefit continues today at the cost of many human lives.

So, let me address this claim from another perspective. Consider the possibility that a treatment is discovered using fetal tissue transplants, and it is the only option for a certain disease. Consider just one disease, like Parkinson's, which affects up to one million people in the U.S. alone. Based on a clinical trial in Sweden, cells from at least three to four fetuses are needed to treat each Parkin-

son's patient. So, four million babies would need to be aborted to treat this one disease, not to mention the number needed to treat patients worldwide.

Imagine the magnitude of the demand for fetuses to cure yet another disease like Alzheimer's, which affects 44 million people worldwide. Do we really want a world where the most vulnerable, those with no voice, are subject to the whims, desires, and perceived needs of others? Clearly, we will have created industrialized harvesting of pre-born babies, a crime against the human race.

Third, the repeated assurances that proper ethical guidelines are in place to avoid the connection between abortion and subsequent research are entirely inadequate. By purchasing fetal tissue products, the researcher is not far removed from the act of abortion. As recently described in the journal Nature, one researcher continues to pay $830 for each fetal liver sample, a purchase he must repeatedly make. A few years ago, before the recent media coverage, it was quite easy to go to the Web site of a biotechnology company and put almost any fetal body part in one's shopping cart and submit for a purchase.

So, independent of whether a researcher is at the bedside of the one choosing an abortion or using a fetal cell line created decades prior, by purchasing these fetal tissue products, scientists are helping to create a market that drives the abortion-biotechnology industry complex.

Mrs. BLACKBURN. Dr. Schmainda, please wrap up. Your time has expired.

Dr. SCHMAINDA. So, finally, I conclude with what is first and foremost. Each and every human life is sacred, with the fundamental dignity that does not depend on his or her development stage or abilities. This value belongs to all, without distinction from the first moment of existence. Each and every human life is unique and unrepeatable, created by our loving God in his image and likeness.

Nothing—no person, no argument, not even a scientific discovery or cure—can diminish the fact that using human embryos or fetuses as objects or means of experimentation constitutes an assault against the dignity of human beings who have a right to the same respect owed to every person.

Thank you.

[The prepared statement of Dr. Schmainda follows:]

Testimony of Kathleen M. Schmainda, PhD.
Professor of Radiology & Biophysics
Vice-Chair of Research, Department of Radiology
Medical College of Wisconsin*

Committee on Energy and Commerce
Select Investigative Panel on Infant Lives
"Bioethics and Fetal Tissue"
2 March 2016

Distinguished Chair and Honored Members of the Panel,

Thank you for the opportunity to offer my testimony in defense of infant lives and specifically in opposition to research using fetal tissue derived from induced abortions.

As background, I was trained in the disciplines of engineering and medicine receiving a PhD degree in medical engineering jointly awarded by Harvard University and Massachusetts Institute of Technology. I am currently a Professor of Radiology and Biophysics, serving as Vice Chair of Radiology Research at the Medical College of Wisconsin. I have participated in medical research for nearly 25 years. I have served on grant review panels for the National Institutes of Health (NIH) for over 15 years, including a four-year term on the Developmental Therapeutics study section. I serve on national advisory committees for clinical trials, and have founded two start-up companies. Most importantly, I am a wife and a mother.

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I am firmly opposed to research using human fetal or embryonic tissue from induced abortions or procedures such as in vitro fertilization (IVF). I am compelled to create awareness amongst the community and my colleagues as to why the use of such tissue is both unethical and unnecessary.

Let me begin by defining terms. The terms embryo, fetus, baby or infant each refer to different stages in the continuum of the developing child. When cells are extracted during the earliest stages these are typically human embryonic stem cells (HESC), which are obtained by destruction of the human embryo. When I speak of fetal tissue research I am referring to cells, tissues or organs that are harvested from an aborted fetus. While this is the focus of my testimony my arguments apply to the continuum of the developing child.

Proponents of research using fetal tissue make several claims. The first claim is that without fetal tissue many of the life-saving treatments we have today would not have been possible. Second, it is argued that without continued access to fetal tissue, we are preventing the discovery of new therapies. And third, it is alleged that 'proper *ethical* guidelines are already in place' to avoid the connection between abortion and fetal tissue research. I will speak to each of these claims.

First, it needs to be made clear that no current medical treatments exist that have *required* using fetal tissues for their discovery or development. While the often-cited polio vaccine was developed using fetal tissue cells, the developers later testified that initial studies were also successful using cells that were not of fetal origin. Though most vaccines today offer ethical alternatives, not all are available in the U.S., and some, such as chicken pox and Hepatitis A, currently do not have ethical alternatives [1]. *Yet there has never been a scientific reason requiring fetal cell lines for vaccine development.*

Testimony given to the FDA (US Food and Drug Administration (FDA), Center for Biologics Evaluation and Research) dated May 16, 2001, underscores this point. The developer of two common fetal cell lines (HEK 293 (human embryonic kidney) and Per C6 (isolated retina from a fetus)) stated that his motivation for developing these cell lines from aborted fetuses was simply to see 'if it could be done' in comparison to what had already been done with animal cells. Since

then, use of these cell lines has become widespread, and the manufacturers have no motivation to invest the time or money necessary to produce ethical replacements.

Due to lack of transparency, scientists can unknowingly become entrenched in using these cell lines. For example, the HEK 293 cell line is often offered as part of a standard kit available from biotechnology companies and branded under various names. Only upon specific request are alternatives provided. This lack of transparency is devastating for scientists who have ethical objections to use of this tissue and amounts to moral coercion.

Second, I refute the claim that that without continued access to fetal tissue, the discovery of new therapies will be prevented. The evidence is overwhelming to the contrary. For example, insulin for diabetes is produced in bacteria [2]. Chinese hamster ovary (CHO) cells have been used for the development of Herceptin for breast cancer [3] and TPA for heart attack and stroke. There are more than 70 successful treatments developed using adult stem cell sources [4]. Over over 1 million bone marrow transplants, which are essentially adult stem cell transplants, have been performed to date [5].

Still some continue to claim that fetal cells unequivocally provide the best option, because they divide rapidly and adapt to new environments easily. But alternative tissue and cell sources are available for research without ethical concerns and are demonstrating more versatility than originally thought [6]. Examples include stem cells from bone marrow, circulating blood [7], umbilical cord [8], and amniotic fluid [9] as well as induced pluripotent stem cells (iPSCs) and even neural stem cells from cadavers [10]. Adult stem cells have already been used for the development of new treatments, have been proven in clinical trials and resulted in the formation of new companies [11] that have successfully brought to market treatments that are routinely benefitting patients today. There is still no viable medical use for embryonic stem cells.

Yet the argument continues that keeping this avenue of research open may some day offer the *only hope* for a child, with a devastating disease or a person with spinal cord injury. In 1997, *The New York Times* reported the nation's first transplant of fetal tissue into a person with spinal cord injury [12]. The study required five to eight fetal spinal cords for each adult recipient but showed no significant therapeutic benefit [13, 14]. Many more studies followed with none showing significant therapeutic benefit yet with each continuing to claim *great promise.* This *promise without benefit* continues today at the cost of many human lives.

So let me address this claim from another perspective. Consider the possibility that a treatment *is* discovered using fetal tissue transplants, and it is the *only option* for a certain disease. Consider just one disease like Parkinson's, which affects up to 1 million people in the US alone. Based on a clinical trial in Sweden, cells from at least 3-4 fetuses are needed to treat each Parkinson's patient [15, 16]. So, 4 million babies would *need* to be aborted to treat this one disease, not to mention the number needed to treat patients worldwide. Imagine the magnitude of the demand for fetuses to cure yet another disease like Alzheimer's, which affects 44 million persons worldwide? Do we really want a world where the most vulnerable, those with no voice, are subject to the whims, desires and perceived needs of others? Clearly we will have created industrialized harvesting of preborn babies, a crime against the human race.

Third, the repeated assurances that 'proper *ethical* guidelines are in place' to avoid the connection between abortion and subsequent research are entirely inadequate. By purchasing fetal tissue products the researcher is not far removed from the act of abortion. As recently described in the journal *Nature* [17] one researcher continues to pay $830 for each fetal liver sample, a purchase he must repeatedly make. A few years ago, before the recent media coverage, it was quite easy to go to the website of a biotechnology company and put almost any fetal body part in ones "shopping cart" and submit for a purchase. So independent of whether a

researcher is at the bedside of the one choosing an abortion, or using a fetal cell line created decades prior, by purchasing these fetal tissue products scientists are helping to create a market that drives the abortion–biotechnology industry complex [18].

Moreover, the demands of research do directly influence the procurement of fetal tissue. The timing of fetal tissue collection, as well as the procedures used to terminate the pregnancy *are* critical to obtaining research-quality tissue and at the right stage of fetal development according to the scientific need. This raises important concerns about whether the health of the mother is appropriately prioritized.

In summary I suggest consideration of the following:

1. Prohibit research using fetal tissue from induced abortions but provide the support and resources necessary to aid scientists or biopharmaceutical companies to make transitions to ethical tissue sources.

2. Support the creation and continued success of institutions or efforts that undertake research using only ethical sources of tissue. Institutions such as the Midwest Stem Cell Therapy Center come to mind. During my years as a grant reviewer for the NIH, I have been continually inspired by the brilliance and innovation of my scientific colleagues. Applying this brilliance in the context of ethical avenues of research should be encouraged and is sure to result in amazing discoveries that prove best for society.

3. Mandate transparency in labeling of all scientific materials, drugs and cosmetic products regarding the source of material used for development or manufacture. This will raise awareness and protect the rights of conscience for scientists, patients, and consumers who do not want to be corrupted by such practices.

Finally, I conclude with what is first and foremost. Each and every human life is sacred, with a fundamental dignity that does not depend on his or her developmental stage or abilities. This

value belongs to all without distinction from the first moment of existence. Each and every human life is unique and unrepeatable, created by our loving God in His image and likeness. Nothing, no person, no argument and not even a scientific discovery or cure, can diminish the fact that using human embryos or fetuses as objects or means of experimentation constitutes an assault against their dignity as human beings, who have a right to the same respect owed to every person [19].

Respectfully,

Kathleen M. Schmainda PhD

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Mrs. BLACKBURN. I thank you. And Dr. Goldstein, you are recognized for 8 minutes for an opening statement.

STATEMENT OF LAWRENCE GOLDSTEIN

Dr. GOLDSTEIN. Good morning—actually, good afternoon, Chairwoman Blackburn, Ranking Member Schakowsky, and other members of the committee. Thank you for the opportunity to testify before you this afternoon about the important and potentially lifesaving research being done with fetal cells and fetal tissue. And I will give you three brief examples for the potential impact of this work.

My bio is in your written materials. I will just summarize a few key points. My early faculty career was spent at Harvard University, where I became a tenured professor. I then moved to the University of California, San Diego in 1993, and I am currently a distinguished professor in the Department of Cellular and Molecular Medicine and the Department of Neuroscience there.

I served as Director of the U.C. San Diego Stem Cell Program, Scientific Director of the Sanford Consortium for Regenerative Medicine, and Director of the Sanford Stem Cell Clinical Center. I have received numerous honors and awards for my work.

I have been a practicing scientist for 40 years, most recently using all types of stem cells to understand and treat Alzheimer's disease, spinal cord injury, ALS, and more recently, kidney disease.

Today, I represent myself and the International Society for Stem Cell Research, the American Society for Cell Biology, and the Coalition for Life Sciences, which together represent in excess of 60,000 practicing life scientists and physicians.

My message is very simple: Fetal tissue and cells that would otherwise be discarded play a vital role in modern, cutting-edge biomedical research. These fetal tissues and cells cannot be easily replaced by embryonic stem cells, reprogrammed stem cells, or adult stem cells. Let me give you three examples.

In the first example, we are using fetal astrocytes in the study of Alzheimer's disease. This devastating disease affects 5.3 million Americans and costs us in excess of $200 billion to $300 billion a year. It killed my own mother. This number doesn't reflect the real and terrible hardship that families face. We don't have a cure. No cure is obviously in sight, and we really do have to find a way to treat this terrible disorder.

Now, in my own lab, the approach we are taking is to use reprogrammed stem cells to make Alzheimer's-type brain cells in the dish. That is, to generate Alzheimer's disease in a dish and to try to understand what is going wrong and to develop drugs that curtail the problems that happen biochemically.

Now, a type of cell that is very valuable in this work is called an astrocyte. And this is a type of cell that is a support cell in the brain. We use fetal astrocytes, which are vital to these investigations. These fetal astrocytes provide growth factors that keep the nerve cells healthy, that help them establish connections, and, to be honest, they produce factors that we do not yet have fully defined that help maintain the viability of these cultures and are proving important to us to make new discoveries.

It is possible to make astrocytes from stem cells. And you can write the label "astrocytes" on those stem cells, but they are not identical in their behavior and properties to fetal astrocytes, which arguably remain the gold standard to which we compare astrocytes made from stem cells. And we cannot yet use astrocytes made from stem cells to replace fetal astrocytes. These astrocytes are vital to our investigations, and I remain hopeful that they will help us conquer the scourge of this terrible disease.

In the second example, in the center that I direct, the Sanford Stem Cell Clinical Center, we are using fetal neural stem cells in clinical trials for spinal cord injury in human patients. In animal versions of spinal cord injury, these fetal neural stem cells have previously been shown to have really remarkable properties, and animals so treated exhibit tremendously greater performance after treatment than before. What seems to happen is that these fetal neural stem cells, when implanted at the site of the injury, make new neurons that form a relay across the site of the injury, enabling these animals to regain function.

Now, as a result of the work in animals, we have FDA approval to test these fetal stem cells in human patients. Physicians and surgeons in my center have initiated FDA-approved phase 1 clinical trials of these cells and have implanted them in four patients within the past year. I will tell you that these surgeries are very arduous and the human volunteers are courageous in the face of uncertainty about their future. Thus far, the trial is a success. We have learned that, at minimum, the surgery is safe. The fetal cells are safe, and we will be tracking these patients over the next few years looking for signs of recovery, as these cells are given the opportunity to develop and positively impact the paralysis.

We hope in the next year to begin transplanting patients with cervical spinal cord injuries, which will give us a more sensitive test bed, we think. This trial and others like it—this is not the only such trial; others are pursuing analogous investigations with different sorts of cells—but these trials are vital to pushing medical science forward and to helping to rescue people who are afflicted with spinal cord injuries, which is a terrible affliction.

I will just mention that these same fetal neural stem cells that we are using for spinal cord injury are also being used in phase 1 and soon-to-be phase 2 clinical investigations for ALS, or Lou Gehrig's disease, at NIH-sponsored centers around the country.

In a third and final example, I chair the executive committee of a group of NIH-funded scientists who are trying to learn whether it is possible to build new kidneys from stem cells. This goal is significant because we have 93,000 Americans on waiting lists for kidney transplants, and we recognize that the goal of building a functional kidney is audacious, but audacious goals build audacious dreams and projects and progress, and I believe that we can attain these goals with hard work, determination, and time. It won't happen instantly, but it is something I think we can achieve.

Fetal tissue that would otherwise be discarded is vital to the future of this investigation, as it is only by examining fetal tissue that we are able to deduce and learn what the signals are that cells use to tell each other which cells are going to become kidneys, which are going to become other parts of the body, and so on.

So, our ability to examine the very earliest stages of human development are ultimately vital to our understanding and our ability to treat many diseases in the future, including diseases of pregnancy, diseases of the placenta, and diseases of children and adults. Development of many of these therapies depends upon our learning what the normal signals are by studying the earliest stages of development and, without this type of research, we will be dramatically slowed down, and people who would have therapies sooner will wait and suffer needlessly longer.

So, let me close by stating once again that, in my opinion, research with fetal tissue and cells that would otherwise be discarded is ethical, valuable, and vital to ongoing biomedical research projects.

I want to thank the committee for your time, and I am prepared to answer questions that you may have.

[The prepared statement of Dr. Goldstein follows:]

HOLD FOR RELEASE
UNTIL PRESENTED
BY WITNESS
March 2, 2016

Statement of
Lawrence Goldstein, Ph.D.
Distinguished Professor, Dept. of Cellular and Molecular Medicine,
Dept. of Neurosciences
Director, UC San Diego Stem Cell Program
Scientific Director, Sanford Consortium for Regenerative Medicine
Director, Sanford Stem Cell Clinical Center, UCSD School of Medicine

before the

Select Investigative Panel
Of the
Committee on Energy and Commerce
United States House of Representatives

Good morning Chairwoman Blackburn, Ranking Member Schakowsky, and other Members of the Committee.

Thank you for the opportunity to testify before you this morning about the important and lifesaving research being done with fetal cells and fetal tissue, and to briefly share three examples of this research, and the potential impact of this research.

Background

My Bachelor's degree in biology and genetics is from the University of California San Diego in 1976.

My Ph.D. in genetics is from the University of Washington in 1980.

I did postdoctoral work at the University of Colorado at Boulder and MIT and was a junior faculty member and then tenured professor at Harvard University until 1993.

I moved to the University of California San Diego in 1993 where

I am currently a distinguished professor in the department of Cellular and Molecular Medicine and the Department of Neuroscience.

I serve as Director of the UC San Diego stem cell program, Scientific Director of the Sanford Consortium for Regenerative Medicine and Director of the Stanford Stem Cell Clinical Center. I have received numerous honors and awards for my work, including election to the American Academy of Arts and Sciences.

I have been a practicing scientist for 40 years, most recently using all types of stem cells to understand and treat Alzheimer's disease, spinal cord injury, ALS, kidney and liver disease, and other terrible afflictions.

On behalf of myself and the International Society for Stem Cell Research and the American Society for Cell Biology, two distinguished scientific and medical organizations with membership of more than 10,000 scientists around the world and based on over four decades of biomedical research experience, it is my

privilege to provide you with up to date and state of the art information about the important value of fetal tissue and cell research.

Research

My message is simple: fetal tissue and cells that would otherwise be discarded play a vital role in modern cutting edge medical research. These fetal tissues and cells cannot be replaced by embryonic stem cells, reprogrammed stem cells, or adult stem cells. These other cell types do not make astrocytes with identical properties as those from fetal sources.

I'll give you three examples of vital cutting edge-state of the art medical research that depends upon the use of fetal tissue and cells that would otherwise be discarded: 1) Alzheimer's disease; 2) spinal cord injury; and, 3) kidney generation.

In the first example, my lab uses human reprogrammed stem cells to develop cells in culture that have the behavior of Alzheimer's disease. This devastating disease afflicts millions of Americans and costs the United States billions of dollars a year in health care costs. This number does not fully reflect the very real and terrible personal costs that so many American families, friends, and colleagues face with this disease. We do not have a cure, nor is one obviously in sight; we must find a

way to successfully treat this terrible disease. In my own lab, we use Alzheimer's disease cells to understand why brain cells with Alzheimer's disease are abnormal and to try to develop drugs. A type of cell that is valuable in this work is called an astrocyte, which is a support cell type in the brain. We use fetal astrocytes, which are vital to these research investigations. These fetal astrocytes provide growth factors that keep nerve cells healthy and other factors that are not yet defined that help the neurons establish connections and maintain long-term growth and viability. Although we can make cells that are similar to astrocytes from stem cells, the fetal astrocytes are the "gold standard" to which we compare astrocytes made from stem cells and which we cannot use yet to replace the fetal astrocytes because they are not identical in capacity to the best of our current knowledge. The fetal astrocytes are vital to these investigations, which I think will help conquer the terrible scourge of Alzheimer's disease.

In a second example, in the Center that I direct, the Sanford Stem Cell Clinical Center, fetal neural stem cells are being used in clinical trials for spinal cord injury in human patients. These fetal neural stem cells have previously been shown to yield remarkable results in animals that have spinal cord injury. These fetal stem cells, when implanted at the site of a spinal cord injury in animals develop into new neurons that appear to function as relays across the site of the injury rendering

the animals able to function in a way that is superior to their performance before the injury. As a result of these investigations, we have FDA approval to test the fetal stem cells in human patients. Physicians and surgeons in my center have initiated an FDA-approved phase 1 clinical trial of these cells and have implanted them in four patients to date. These surgeries are very arduous and the human volunteers are courageous in the face of uncertainty about their future. The trial is a success thus far. We have learned that at a minimum the surgery is safe and the fetal cells are safe. We will track the patients over the next few years to observe what we are hopeful will be evidence of beneficial effect on the patients' paralysis. Our next goal is to advance this trial to cervical spinal cord injuries soon . We hope to see evidence of positive impact on these patients as time progresses over the next 3-5 years. This trial and others like it are vital to pushing medical science ahead in our attempts to cure spinal cord injury, which is a terrible affliction to patients and the families who care for them. These same fetal neural stem cells are also being used in NIH clinical trials at various sites around the country for another incurable and devastating disease called ALS or Lou Gehrig's disease.

In a third example, I chair the executive committee of a group of NIH-funded scientists who are working together to try to learn whether it is possible to build new kidneys from stem cells. The hoped-for building of new kidneys is significant

because 93,000 Americans are on waiting lists for kidney transplant. The goal of building a functional kidney is audacious, but one that I believe can be obtained with hard work, determination, and time. Fetal tissue that would otherwise be discarded is vital to the future of this investigation as it is only by examining this fetal tissue that it will be possible to determine the earliest biochemical signals that cells use to tell some cells to make kidneys and other cells to make other organs.

Our ability to examine the earliest stages of human development are vital to our understanding and our ability to treat many diseases in the future including diseases of pregnancy, diseases of the placenta, and diseases of children and adults. Development of many of these new therapies will rely on our learning and understanding of the proper developmental signals that cells use at the earliest stages of development. We must continue to use fetal tissue that would otherwise be discarded and that is a window into the early stages of human development. Without fetal tissue, vital research such as the examples I have shared with you will be slowed down that would otherwise lead to therapies and vaccines sooner in the future and which could literally be life changing for individuals and their families in the future.

Summary

Let me close by stating once again that in my opinion research with fetal tissue and cells that would otherwise be discarded is ethical, valuable, and vital to ongoing biomedical research projects. If we do not continue to use this tissue that is destined for discard, we forego the ability of researchers to continue to make timely and significant progress in mitigating if not eliminating devastating diseases like Alzheimer's and improving the quality of life of many people in the future.

I want to thank the Committee for allowing me the opportunity to share a researcher's perspective on the importance of fetal tissue and cells to biomedical research.

Chairwoman Blackburn, I would be pleased to respond to any questions you or the other Members of the Committee may have regarding my research.

One page summary of the testimony of Dr. Lawrence S. B. Goldstein to the Select Investigative Panel on Infant Lives Of the Committee on Energy and Commerce, United States House of Representatives

1) Dr. Lawrence S.B. Goldstein is a highly qualified scientist who is knowledgeable about the value of fetal tissue research.

2) Research with fetal tissue that would otherwise be discarded has great value in research on many different diseases including Alzheimers disease, spinal cord injury, ALS and others.

3) Research with fetal tissue that would otherwise be discarded may help us learn how to construct new organs from stem cells.

4) Research with fetal tissue that would otherwise be discarded cannot be replaced by research with other types of cells or with animals.

Mrs. BLACKBURN. Thank you, Dr. Goldstein.

We will move to questions. And on our side, I am going to reserve my time and Joe Pitts, Chairman Pitts, will be recognized for 5 minutes.

Mr. PITTS. Thank you, Madam Chair. Thanks again to the witnesses for coming today.

Let me just say something for the record that wasn't covered in the last panel. The issue of undercover journalism was raised, but I just want to put this quote on the record. The indictment was alarming enough for two pro-abortion scholars at Cornell to write an opinion piece defending undercover journalism. Professors Sherry Colb and Michael Dorf said, "We are pro-choice, and we support the important work of Planned Parenthood, but we find the prosecution of these citizen journalists, however self-styled, deeply disturbing. Undercover exposés play a vital role in informing the American public of important facts that would otherwise remain hidden."

We are all familiar with local TV station I-teams and undercover exposés using hidden cameras, sometime false narratives. Mike Wallace was famous—journalists have gone undercover to expose shoddy conditions at the VA hospitals. Nick Kristof of The New York Times posed as a customer to reveal the darkness of sex trafficking in Cambodia, and you can go on and on. So, for the record, I will put that.

Now, let me go to this question. The gentleman mentioned Harvard. I think using—whether fresh, fetal tissue is vital to cures is an open question. Presently, Harvard has 8,000 medical research projects underway, only 10 use fresh fetal tissues; 10 out of 8,000.

Now, some defend the practice of fetal tissue collection from aborted babies because the fetal tissue supposedly contributes to life-saving research today. First, can you tell us what deadly diseases have been cured or can now be treated thanks to modern-day collection of human fetal body parts, anyone? No?

And secondly——

Dr. GOLDSTEIN. No, I think——

Mr. PITTS. I am sorry?

Dr. GOLDSTEIN. I would like to respond because I think the case of vaccines is appropriate. The fact is, that is how those vaccines were developed.

Mr. PITTS. Which vaccines?

Dr. GOLDSTEIN. Polio and the other long list that Professor Charo gave us. And it is so easy to look in the rearview mirror at research and say, "Well, now that we know everything we know, it would have been so much easier to do it a different way, you didn't have to do it this way," but the fact is, as you well know, research is a slow, tough enterprise.

Mr. PITTS. Yes, reclaiming my time. The simple fact is that the vaccine for polio was developed using monkey tissue, not human fetal tissue.

Let me go on to my question, and it has to do with conflict of interest. Suppose a tissue procurement business makes financial contributions to an abortion clinic from which the company harvests tissue. What ethical issues exist if the clinic notifies the company in advance that the clinic has particular abortions scheduled

that would be good for acquiring particular organs or tissue? Dr. Lee.

Dr. LEE. Can you help me with who is making the contribution to whom again?

Mr. PITTS. The procurement business——

Dr. LEE. Is making the contribution to the abortion clinic?

Mr. PITTS. Yes.

Dr. LEE. OK. Well, I think there is a conflict of interest in that there is not the separation. I think in all of these organ transplant cases, we want to have a different set of team making the decisions about how to proceed, how to treat a patient, and then a different set of team from that on talking to the family about whether to make a donation. And it seems to me it is the same team here that is working on aborting this baby that is also trying to get the consent from the woman, which I think is questionable whether it has authority there, but getting consent from that woman to use the fetal body parts.

So, I think there is a conflict of interest there, yes.

Mr. PITTS. Dr. Schmainda?

Dr. SCHMAINDA. Yes, there is definitely a conflict of interest, and I would like to also add with regard to the procurement of tissue, I oversee a tissue bank for brain tumor tissue and spinal cord tumor tissue. And our procedure is such that we have to have someone constantly on-call with a pager, and they have to be there in the OR, ready to go 30 minutes from tissue removal. And if you don't get that tissue within 30 minutes of removal, it is no longer useful for research, especially the more advanced research like genomics and proteomics.

So, it is very difficult to see how there can be a separation between the research and the requirements of the scientific community and the act of procuring that tissue.

Mr. PITTS. My time has expired. Thanks.

Mrs. BLACKBURN. The gentleman's time has expired. Ms. Schakowsky, you are recognized for 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you.

Ms. Schmainda, you oppose the use of fetal tissue in scientific research, right?

Dr. SCHMAINDA. Yes.

Ms. SCHAKOWSKY. Is this the position your university has?

Dr. SCHMAINDA. I represent my own views. I am not representing my university.

Ms. SCHAKOWSKY. In fact, last September, Dr. John Raymond, the President and CEO of your university, testified in opposition to a Wisconsin State Senate bill that would prohibit researchers in the State from using fetal tissue in their research.

Dr. Goldstein, so my colleagues have used documents, emails from researchers seeking fetal tissue, and I don't know, maybe it is in an effort to shock us, but what is your feeling about asking for, for example—it may not sound great—but a liver or a thymus, that kind of thing, if you have specific research going on? Do you see anything unethical about that?

Dr. SCHMAINDA. Absolutely.

Ms. SCHAKOWSKY. No, I am asking Dr. Goldstein that.

Dr. SCHMAINDA. Oh, excuse me.

Dr. GOLDSTEIN. No, I don't see anything unethical about asking for specific regions. When we get brain tissue from our Alzheimer's disease brain bank, we will request the hippocampus or a part of the cortex, or a specific part of the brain as part of the normal procedure for obtaining post-mortem tissue.

Ms. SCHAKOWSKY. Thank you. So, I wanted to ask you, there have been concerns about the recent outbreak of Zika, of course, and it has led to renewed focus on infectious diseases that have the potential to rapidly spread. As you know, there seems to be a strong link between Zika virus infection during pregnancy and congenital microcephaly, a devastating birth defect. And at this point, there is no treatment or vaccine for Zika.

Given the majority's insistence on calling this panel the Select Investigative Panel on Infant Lives, it would seem important to focus on potential ways to improve infant lives, like finding a way to prevent or cure the Zika virus and the potential for microcephaly. In fact, the CDC has recently released guidance on the collection and submission of fetal tissue for Zika virus testing. They recognize that the study of this tissue is the means through which we can understand the virus.

So, Dr. Goldstein, how are we expected to learn and understand the implications of the Zika virus without studying the fetal tissue?

Dr. GOLDSTEIN. I think that if you want to understand the Zika virus, the most efficient place to start is with the fetal tissue that is infected. That just seems self-evident to me.

Ms. SCHAKOWSKY. Isn't it imperative that researchers have access to brain tissue to study the differences between the healthy neurological cells and those potentially infected with microcephaly?

Dr. GOLDSTEIN. Well, and in particular for figuring out which cell types are infected. It is often forgotten that the brain is made of dozens, if not more, kinds of cells. We don't know which cell type is being infected by the virus, and it is only by surveying the landscape that we will get any clues.

Ms. SCHAKOWSKY. The World Health Organization has now labeled the Zika virus as a "public health emergency of international concern." What is your view of preventing the use of fetal tissue research to study and hopefully stop this growing public health emergency?

Dr. GOLDSTEIN. I think that would be sticking your head in the sand.

Ms. SCHAKOWSKY. Thank you. Would not having fetal tissue as a resource in this study potentially delay finding a cure?

Dr. GOLDSTEIN. It would absolutely delay it. I think you have to go to the source if you want to understand what is going wrong.

Ms. SCHAKOWSKY. Going back to the name of this committee, this type of research could lead to treatments and cures that benefit infant lives, could it not?

Dr. GOLDSTEIN. That would be the hope. You know, there is never any guarantee with research that we are going to get to where we want to go, but we are going to give it a good solid try, and we have to have appropriate tools.

Ms. SCHAKOWSKY. Beyond Zika virus, fetal tissue is important for research and to other conditions that impact infant and fetal

development. Is that correct? And I am wondering if you could name what else we might be investigating.

Dr. GOLDSTEIN. Well, another interest in my lab is in a disorder called Niemann-Pick type C1, which is a devastating cholesterol transport disorder that kills kids in their first or second year of life. We use fetal astrocytes in our investigation of that disorder, as well. We have recently discovered what I hope will be two drugs that may be effective. We need to get into clinical trials to find out, but it is the sort of thing that you could imagine doing on multiple occasions down the line.

Again, research is not a guarantee, but we have to go through the door and look in order to find out.

Ms. SCHAKOWSKY. Thank you, and I yield back.

Mrs. BLACKBURN. Mrs. Black, you are recognized for 5 minutes.

Mrs. BLACK. Thank you, Madam Chair, and I thank the panelists for being here. I think it is really ironic that we sit here and talk about how we will benefit children and, at the same time, we are talking about how it is OK to abort a baby and to dissect it and take out its body parts and use that for research but, at the same time, we talk about how this will save babies. So, it is very ironic. Do we want to save babies, or do we not want to save babies? But that is not my question.

My question I want to go to are babies that are born alive in these abortion clinics. And just last week, there was a 20-week-old child that was born alive in a Phoenix abortion clinic. There was a fire department that was close and had to transport the baby to the hospital.

Since sometimes these children are born alive, either during or right after the abortion, should abortion clinics have neonatal care equipment in those clinics to help to save those babies? Dr. Lee, do you have a thought on that?

Dr. LEE. Yes. I mean, I think that if we were treating someone that we really genuinely recognized as a human being and as having intrinsic dignity, we would say that we need to have available the kind of care that is needed if something goes wrong. And we would not fight every inch of the way when the Government, whether it is State or Federal level, tries to require protection for babies who are born alive.

So, yes, I think neonatal care, access to ambulance care, I think that is a minimum, I think.

Mrs. BLACK. Dr. Schmainda, do you have a thought on that?

Dr. SCHMAINDA. I can't imagine it because, when you have the neonatal care unit, you are recognizing that this is a human person. And I think absolutely it must be because it is a human person, it would be wonderful if it existed.

Mrs. BLACK. How about you, Dr. Goldstein, do you have a thought on that?

Dr. GOLDSTEIN. I am not an expert on the sort of equipment that should be present at an abortion clinic, and it would be inappropriate for me to speculate.

Mrs. BLACK. Well, can I ask you do you think it is wrong to let a child die that is born in an abortion clinic and needs medical assistance?

Dr. GOLDSTEIN. I think it is wrong to let a child die.

Mrs. BLACK. Thank you.

The second question that I have along these lines: Should the mother be told as a part of that consent form that there is a chance that your baby will be born alive and that our clinic will give your baby the best care? Ethically, what do you think about that, Dr. Lee?

Dr. LEE. Well, I think it is hard to say when you are talking about percentages, and it is a difficult question to answer because the premise of it is that we are talking about asking someone full consent for something that I think, if they genuinely understood and had a moral outlook, a just outlook, they would not really want to consent to that.

So, it is kind of a—I find it difficult to answer that question. But I would say that I think, in general, there is not enough information given to the woman about the nature of what it is that is being killed in an abortion. Sometimes it is even hidden from her that anything is being killed, that there was even something alive. So, if we could just get even just general really good informed consent about the nature of that procedure that we are talking about, that would be a first step. And then, yes, I think the other things should be brought in, when you are talking about the possibilities. Even if it is a remote possibility, it is such a horrific possibility and it also, I think, bears on the question that she should be asking about, Well, what kind of procedure is this?

Mrs. BLACK. Thank you. With the little bit of time that I have left, Madam Chairman, I am not so sure after we complete our investigations and our information that we will receive as a result of this committee that there shouldn't be another blue ribbon commission. We talked about this blue ribbon commission that was under President Reagan, it was done back in 1984. We are 30 years down the road. There is so much medical science advancement here. At that point in time, the viability—I was still young out of nursing school, the viability was around 36 weeks. And, you know, if we had a baby that was born at 36 weeks or less, we really didn't have a lot of medical advancements for saving that child. But I think that this whole issue really needs to be revisited and, rather than going back and looking at a blue ribbon commission that was done some 30 years ago, that may be one of the recommendations that we have.

And I yield back the balance of my time.

Mrs. BLACKBURN. The gentlelady yields back.

Ms. DeGette, you are recognized for 5 minutes.

Ms. DEGETTE. Thank you, Madam Chair.

As with the last panel, I would appreciate yes-and-no answers, if possible.

My first question, Dr. Lee, you are a professor, a doctor of philosophy, correct?

Dr. LEE. Right.

Ms. DEGETTE. And Dr. Schmainda, you have a Ph.D. in medical engineering. Correct?

Dr. SCHMAINDA. Correct.

Ms. DEGETTE. And the first line of your biography on the Medical College of Wisconsin's Web site says your primary focus of your

lab is the development of MRI methods to assess brain tumors. Is that correct?

Dr. SCHMAINDA. That is definitely a focus, yes.

Ms. DEGETTE. Now, Dr. Goldstein, you are an actual cell-based researcher and you run a lab. Is that correct?

Dr. GOLDSTEIN. Yes.

Ms. DEGETTE. So, I am going to talk to you, since of all the six witnesses we have had today, you seem to be the only one with experience in being able to talk about fetal tissue research and other types of cell-based research.

The first question I want to ask you is, Dr. Donovan said we still have cell lines developed from fetal tissue from abortions from before and from a long time ago, when they were used for vaccines and other purposes; those should still be sufficient. Do you believe that existing fetal cell lines are sufficient, or do you think it is important to develop new fetal cell lines?

Dr. GOLDSTEIN. I think that as methods improve, you generally are going to want to revisit the question of developing new cell lines with superior methods.

Ms. DEGETTE. Now, in the three studies you talked about in your testimony, are you using new cell lines or some of the existing cell lines from before?

Dr. GOLDSTEIN. The fetal neural stem cells, those are cell lines that have been in existence for some time and have been through substantial expansion. The fetal astrocytes are earlier stage primary cultures, but they are also established.

Ms. DEGETTE. OK. And my next question and related to that is, Dr. Schmainda said that there is no—actually, she said in her testimony it is clear that no current medical treatments exist that have required using fetal tissues for their discovery or development. Is that a correct statement, "yes" or "no"?

Dr. GOLDSTEIN. I think that is an incorrect statement.

Ms. DEGETTE. OK. Now, there are a number of new research studies, including the ones that you and your facility are investigating, that are using fetal cells. Is that correct?

Dr. GOLDSTEIN. That is correct.

Ms. DEGETTE. And several of the witnesses today have testified that the cell lines are all interchangeable, so that, to do your research and this other research, you would not need to have fetal cells. Is that correct?

Dr. GOLDSTEIN. I don't agree with that. In my experience, cell lines are simply not interchangeable.

Ms. DEGETTE. And I know there are a number of new types of cell lines out there. I have done a lot of work, as you know, on embryonic stem cell research, but there are a lot of different kinds of cells. There are iPS cells, there are human mesenchymal stem cells, there are some nasal astrocytes that are being used in other types. Can they all just be slotted in for each other, or do you need all different types of cells to do research?

Dr. GOLDSTEIN. So, I will make two comments about that. One is we need all different types of cells to do research because we don't know what is best. And second, in order to find out what is best, we have to do comparative studies and compare each against

the other to figure out what is actually going to turn out to be superior for the medical application.

Ms. DEGETTE. So, it is not like the iPS cells are the same thing as these fetal tissue cells?

Dr. GOLDSTEIN. No. No, no, they are different.

Ms. DEGETTE. OK. Now, there was also some testimony from several different of the witnesses, none of them cell researchers like you, that we don't need fetal tissue from induced abortions because we can just use fetal tissue from miscarriages. Have you heard testimony like that today and before?

Dr. GOLDSTEIN. I have heard that statement made.

Ms. DEGETTE. And are you familiar with the view that, because the timing of recognition of a spontaneous abortion or ectopic pregnancy is unpredictable and both conditions may result in a serious emergency for the woman, the fetal tissue collected under these circumstances is often not suitable for research purposes? Are you aware of that?

Dr. GOLDSTEIN. I am aware of that.

Ms. DEGETTE. And do you think that we can substitute the tissue from spontaneous abortions or from ectopic pregnancies?

Dr. GOLDSTEIN. I don't.

Ms. DEGETTE. Why not?

Dr. GOLDSTEIN. And I would add that frequently spontaneous abortions have genetic abnormalities that render them unsuitable for further downstream work.

Ms. DEGETTE. Thank you. I have no further questions.

Mrs. BLACKBURN. The gentlelady yields back.

Dr. Bucshon, for 5 minutes.

Mr. BUCSHON. Thank you very much. Thank you to all the witnesses for being here. By the way, I did my residency at the Medical College of Wisconsin, and I spent 7 years there. My wife went to medical school there. Welcome, all of our witnesses.

Dr. Goldstein, in your testimony you failed to mention that functional kidney organoids have already been grown using iPS cells and adults stem cells. Is that true?

Dr. GOLDSTEIN. It is true that organoids have been made. An organoid is not the same as an organ. In fact, Dr. Little, in whose lab that work was done is a member of our team——

Mr. BUCSHON. OK. Now——

Dr. GOLDSTEIN [continuing]. Trying to figure out how to harness organoid technology to the development of an intact functional kidney.

Mr. BUCSHON. That is fair enough. So, with fetal cells then, you are trying to grow organs?

Dr. GOLDSTEIN. Ultimately, the goal would be to figure out whether using fetal cell lines, or embryonic cell lines, or induced reprogrammed cell lines, whether it is possible to build a functional kidney or not.

Mr. BUCSHON. OK. And the same thing, if you have already made it to organoids from iPS cells and adult stem cells, it seems like you are actually further along in that area using those.

Dr. GOLDSTEIN. I am not sure I agree with that. I think that is conjecture.

Mr. BUCSHON. OK, well that is your area. So, I can't dispute that.

You mentioned fetal cells related to spinal cord injuries. Are there peer-reviewed journal studies about clinical cures of spinal cord injuries from adult stem cells?

Dr. GOLDSTEIN. There are published papers from a number of labs around the world that claim to have seen dramatic results with cells from adult sources in spinal cord injury. In a number of cases, those studies have been discredited. In a number of cases, we are just not sure and we need to have further investigation to find out.

Mr. BUCSHON. OK, thank you. And can I ask, where do you guys get your fetal tissue?

Dr. GOLDSTEIN. So, the fetal neural stem cells that we obtain for our clinical trials come from our collaborating company called Neuralstem, which expands them to a large number, literally billions of cells.

Mr. BUCSHON. OK, where do they get the tissue to start their cell growth?

Dr. GOLDSTEIN. I honestly don't know where they obtain their tissue.

Mr. BUCSHON. Do they pay for it, do you know?

Dr. GOLDSTEIN. I don't know, but I presume that since it is against the law for them to pay for it, that they do not pay for it.

Mr. BUCSHON. OK. And so somebody made the point that, since tissue would otherwise be discarded—I am just asking, this is a philosophical question—should anyone be paying for fetal tissue or making a profit from it, since it was just going to be "discarded" anyway? The reason I ask that is because we know there are agencies that have been making a lot of money off of this tissue. So, just philosophically, would you think that that would be the right thing, that money should be exchanged? I mean, I understand that the argument is that it takes money to process the tissue.

Dr. GOLDSTEIN. Right, exactly. So, I am comfortable with the law of the land as it currently sits.

Mr. BUCSHON. OK. Dr. Schmainda?

Dr. SCHMAINDA. Yes.

Mr. BUCSHON. That same question. If the tissue is just discarded, I mean, does it make any ethical sense that people would be making a profit from it if it is just—as has been quoted by many people, a couple people in this hearing—it is going to be discarded anyway, what is the big deal? Then how come we are selling it and making a profit from it?

Dr. SCHMAINDA. Right, the ends never justify the means.

Mr. BUCSHON. How come we are buying it?

Dr. SCHMAINDA. Exactly. So, while the ends never justify the means, supposedly, the guidelines are in place and so the researchers are not connected with abortion. They clearly are by creating the market that is driving the development of these cell lines or the use of fetal cell tissues. The biopharmaceutical company, there is a lot of areas where people could be making a lot of money. So, it is clear that is a moneymaking effort.

And I also want to speak to the fact that, if you don't mind, there has been a lot of discussion of the 1988 Advisory Panel, this blue

ribbon panel that people have been discussing. And I want to clarify because, in my reading of this panel, there are actually 21 panel members and, of the 21, there were two or three that dissented from the majority opinion. Now, the majority opinion itself basically was that we agree that there is a moral question here.

Mr. BUCSHON. OK. I am going to have to move on because I am running out of time.

Dr. SCHMAINDA. OK.

Mr. BUCSHON. Dr. Lee, do you have any comments on that question about—I mean, it is just, like, it makes no sense to me that, if there is no money in this, the tissue, and it is about research—and I support research. Don't get me wrong and Dr. Harris addressed that in the last panel—then why are there organizations out there wanting to do this? If there is just no money involved, it is going to be discarded anyway, what is the big deal? We will just use it for research.

Dr. LEE. Well, my comment is, if the argument that the fact that these would be discarded anyway had any merit, it would prove too much. It would prove that, well, then, since it is going to be discarded anyway, we might as well allow people to make money off this. In any situation where someone dies who did not consent to have his body used for research, the same argument could be made about that person's body and say, well, look, yes, it is true that person did not give consent——

Mr. BUCSHON. Understood. My time has expired. Thank you very much.

Mrs. BLACKBURN. I thank the gentleman.

Ms. Speier, you are recognized for 5 minutes.

Ms. SPEIER. Thank you all.

Dr. Lee, again, you are not a researcher. Correct?

Dr. LEE. Not in physical science.

Ms. SPEIER. Not in physical science, and yet this hearing is about the use of fetal tissue in a scientific setting.

Dr. LEE. Right, my area of study is bioethics.

Ms. SPEIER. It is a little confusing to me as to why this panel, which should be comprised of scientists, doesn't have a whole panel of scientists. But, you are an ethicist. So, let me ask you this.

One of the questions one of my colleagues asked was, Is it unethical for a tissue procurement facility to contribute to an abortion clinic? And you gave an answer. Do you think it is ethical for Members of Congress to receive campaign contributions and then vote for a specific bill from that institution or carry a bill for that institution?

Dr. LEE. I would have to get more specifics by—meaning a bill for that institution. I don't know. If it is a bill, yes, I guess. If you are saying if the bill is precisely not for the public good but for only this specific institution, yes, that would be unethical. But then, of course, that just raises the question of whether we are talking about the public good or whether we are trying to promote a specific institution. And I think that——

Ms. SPEIER. Well, thank you. Thank you for your comments. This is kind of preposterous for us to sit up on this committee and suggest about ethical behavior when we are in the business of cam-

paigning and raising money from individuals who are interested in getting us to vote one way or another.

Let me ask you, Dr. Goldstein, 41 academic institutions have written a letter emphasizing the need for continued fetal tissue research. In your own words, can you explain what is at stake if this research is not permitted to continue?

Dr. GOLDSTEIN. Predicting the future is a very dodgy business, and any of us who claim to predict the future have got to do so cautiously, but I think it is fair to say research into deadly disease will slow down. And that is not virtual. If I am 2 years later finding a therapy for a disorder, that is 2 years' worth of people who will have developed that disorder and passed away from it.

I think back to Christopher Reeve, with whom I testified some years ago in an embryonic stem cell hearing, and we talked at that time about what was at stake for people like Mr. Reeve. And the fact was, time was at stake. So, he, sadly, did not live long enough to see us putting an appropriate fetal neural stem cell type into clinical trial. I am sorry about that, because I think he would have been really heartened to see that, and he ran out of time.

Ms. SPEIER. I was very impressed by your work with spinal cord injuries. There are many people who are paralyzed, whose life, quality of life, has diminished greatly. The work you are doing right now where you are using fetal neural stem cells has the potential, does it not, to create a means by which individuals in the future who are living in a paralyzed state could in fact have fuller function?

Dr. GOLDSTEIN. That is the potential, if everything goes according to plan.

Ms. SPEIER. There was a reference made earlier about reconstruct—of cosmetic purposes that fetal tissue could be used for. It was interesting that my colleague didn't reference the word "reconstructive" and cosmetic purposes. And I think we fail to appreciate that skin grafts are used in very important reconstructive purposes. Persons who are burn victims benefit by the use of skin grafts. I, personally, have a body that is full of skin grafts due to an injury I received over 36 years ago. So, let's not diminish or somehow dilute the importance of the use of skin grafts in the effort to potentially improve people's lives.

I am also concerned—and I have only got 20 second left, so Dr. Goldstein, I am concerned about the chilling effect on researchers who are now being called, much like the McCarthy hearings of old, to have their names associated with research they are doing. Could you speak to that?

Dr. GOLDSTEIN. I think the chilling effect of naming names is always a danger of this sort of proceeding.

Ms. SPEIER. Thank you. I yield back.

Mrs. BLACKBURN. The gentlelady yields back. Dr. Harris is recognized for 5 minutes.

Mr. HARRIS. Thank you very much.

Dr. Schmainda, let me just clarify, because I think a question was asked of you before, Do you oppose tissue cell—fetal tissue research? But your summary says that you believe that we should prohibit research using fetal tissue from induced abortion. Is that the correct summary?

Dr. SCHMAINDA. Correct.

Mr. HARRIS. OK, because we are frequently painting with a broad brush that somehow we all oppose this life-saving fetal tissue. We are talking specifically——

Dr. SCHMAINDA. Yes.

Mr. HARRIS [continuing]. About induced abortions.

Dr. SCHMAINDA. Absolutely.

Mr. HARRIS. So now, you have done medical research for 25 years and, although your qualifications have been questioned to sit on this panel, since this panel is bioethical issues, I take it you have filled out IRB consents before?

Dr. SCHMAINDA. Yes, all the time.

Mr. HARRIS. OK. And the purpose is to ethically protect patients, right?

Dr. SCHMAINDA. Correct.

Mr. HARRIS. So, I am going to ask Exhibit A–3 to be put up again, which is the donation form that comes from a clinic where this fetal tissue is obtained. And I will tell you—and I am sure when you have obtained consent for research you are careful not to over-promise because that, of course, would induce a patient to accept and consent to research.

So, I am going to read the first line. It says, "Research using the blood from pregnant women and tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS."

And I am going to ask Dr. Goldstein in a second, we really have found a cure using fetal tissue for diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS? Because that is exactly what this form says. And if I had made this promise to a patient I was obtaining consent for, my IRB would never allow me to say that what we are doing has found a cure. Is that what your IRBs would do?

Dr. SCHMAINDA. Absolutely. Yes, we can——

Mr. HARRIS. That is what I thought. Let me just keep going because I have limited time and I do want to ask Dr. Goldstein a few questions because I personally am not—Dr. Goldstein, look, thank you for your willingness over 40 years to look into these diseases that affect human beings. No question about it. I was medical research. You are medical research. Again, I am not going to relitigate use of fetal tissue because I think we have a broad agreement that fetal tissue ethically obtained is absolutely appropriate.

First of all, you have suggested that anything that slows this process down is a bad thing. You kind of suggested that. You have an IRB. How long does it take your IRB to approve, normally? Mine took months. I know exactly why you are laughing. It can take months or even a year, can't it?

Dr. GOLDSTEIN. That is right.

Mr. HARRIS. OK, so——

Dr. GOLDSTEIN. And if I might chip in here——

Mr. HARRIS. No, you can't. I have got to keep going because I have a bunch of questions. And I appreciate that you are totally honest about that.

So, we have already made the decision that it is all right to slow down life-saving research when it involves humans for ethical rea-

sons because we have a national policy that you have to have an IRB, which we know slows down life-saving research.

So, the question is not whether it is all right to slow it down. It is whether it is ethical, to assure ethics.

In an article in Nature magazine in December, I am sure you know you have said this, regarding aborted fetuses, you said, "We are not happy about how the material became available but we would not be willing to see it wasted and just thrown away." And I am just going to concentrate on the quote, "We are not happy about how the material became available." Why? Why are you not happy about how that material became available? Is that an accurate quote? I know sometimes the press misquotes us.

Dr. GOLDSTEIN. It is an absolutely accurate quote, and I think probably the best way to think about it is I don't seek out controversy. I am happier if my research just happened in a quiet back room and I could get on with the business of looking for therapies.

Mr. HARRIS. And that is every researcher I have known in medicine has felt the same way. So, I absolutely understand that opinion.

I have got to tell you and, again, you have been brutally honest with us, and I thank you for your honesty.

It has been suggested that it is immoral for these tissues to be discarded. Literally, I mean we can replay the transcript, that it is immoral. Do you agree that, if one of these patients doesn't sign this form and that the tissue is discarded, that woman is making an immoral decision?

Dr. GOLDSTEIN. May I answer?

Mr. HARRIS. Absolutely.

Dr. GOLDSTEIN. It is up to the patient to make that decision.

Mr. HARRIS. But is it immoral if the woman chooses not to make the donation?

Dr. GOLDSTEIN. No, it is not immoral.

Mr. HARRIS. Thank you. Thank you very, very much for that honesty.

And I am just going to ask Dr. Lee, because you are a bioethicist, is that form ethical where you tell a patient that diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS, that this tissue has been used to find a cure? Past tense. It is not "we are going to use it to attempt to find a cure," it "has been used to find a cure." English has a very specific meaning. Is that unethical to ask this woman at a time when she is making a difficult decision to say that this tissue has been used to cure diseases when it hasn't?

Dr. LEE. No, in order to make a fully informed consent, you have to be given accurate information.

Mr. HARRIS. Thank you very much. I yield back.

Mrs. BLACKBURN. The gentleman yields back.

Ms. DelBene, you are recognized.

Ms. DELBENE. Thank you, Madam Chair.

I think everyone agrees that medical research using human tissue should adhere to ethical standards. There is no disagreement. But, as Dr. Goldstein and every researcher in America knows, that is true for all human tissue. If I wanted to donate tissue as part of a research study, the use of my tissue would be overseen by an Institutional Review Board and subject to strict ethical and legal

rules. I am an organ donor. I assume many people in this room are organ donors. And, if an accident took place and any of us were in a position where our organs would be donated, the use of our organs to save someone else's life would rightfully be subject to similar ethical guidelines. Rules guiding scientific research should be crafted in a reasonable and deliberate manner, and they should be crafted by science, not by ideology.

As Professor Charo pointed out, diseases also do not discriminate. The majority's attacks on research are an attack on all Americans' health, because nearly everyone in this country has benefitted from research involving fetal tissue.

Dr. Goldstein, as you know, medical breakthroughs come after years of incremental progress, often starting with very basic research that was conducted sometimes for an entirely different purpose and we learned something that was very relevant to move forward in a different area. Our greatest discoveries might have gone undiscovered if we cut off avenues of basic research that didn't seem promising at the time. So, how would you respond to claims that this research isn't useful or necessary anymore?

Dr. GOLDSTEIN. Well, I don't disagree that it is not useful or not necessary any longer. And the fact is, as you correctly recognize, of 100 times that we start testing the therapy, 90 or 95 percent of the time it is a dry well. We fail more often than we succeed, but we persist. What we learn from the failures is important to help us figure out how to be successful in the future.

Ms. DELBENE. So, to clarify, you do think that it is useful and necessary to continue this type of research.

Dr. GOLDSTEIN. Oh, absolutely, yes.

Ms. DELBENE. If Republicans were successful in cutting off this research, would potential for medical breakthroughs be slowed or stopped altogether?

Dr. GOLDSTEIN. It would be slowed.

Ms. DELBENE. And could you speak about some of the work that is going on right now, the ongoing research in this area?

Dr. GOLDSTEIN. Well, I mean, if our clinical trials with fetal neural stem cells in spinal cord injury were halted, I think that would be a terrible shame because I think it is one of our most promising avenues. It is not just us that have seen these properties with these cells. It has been repeated in other labs. It looks like a very good, fertile ground, and I would hate to see it stalled. The same for our work on Alzheimer's.

Ms. DELBENE. Do you think there would be ethical implications to not continuing that type of research?

Dr. GOLDSTEIN. You know, we owe it to our descendants what kind of world we give them. And I know that can be taken in a variety of different ways, but we are following the law. We are doing work that has been deemed ethical by the mainstream scientific community, and it is work that looks as though it is going to be very promising.

I wonder if I might give you one comment. In Parkinson's disease, fetal tissue research is sometimes pointed to as having not been successful because it didn't yield, in and of itself, a cure. The fact is, that fetal tissue research has taught us what now to do with embryonic stem cells and perhaps with reprogrammed stem

cells. So, even in that case, we learned a lot about how not to do things, how to avoid overdosing tissue, what types of cells to make in the future.

Ms. DELBENE. I agree. I did medical research when I started my career, and sometimes the things that didn't go as you anticipated actually yield the greatest learning.

Dr. GOLDSTEIN. Yes.

Ms. DELBENE. Folks brought up earlier that there has been a series of subpoenas and sweeping overbroad document requests to many names of patients, doctors, medical students—all who are involved in women's health care and vital medical research—without really any legitimate reason for doing so. I wondered if you believe that that kind of environment is conducive to academic freedom and scientific advancement.

Dr. GOLDSTEIN. No, I think it is terrible when researchers have to worry about their personal safety.

Ms. DELBENE. And do you think the political climate can have a chilling effect on scientific research going forward if that continues?

Dr. GOLDSTEIN. It is already having it.

Ms. DELBENE. It is already having it. In what way are you seeing that today?

Dr. GOLDSTEIN. So, there is another project that I am involved with that has basically seen a supply of fetal material dry up completely, and it was a very promising therapy for MS.

Ms. DELBENE. Thank you. My time has expired. I yield back, Madam Chair.

Mrs. BLACKBURN. I thank the gentlelady.

Mrs. Hartzler for 5 minutes.

Mrs. HARTZLER. Thank you, Madam Chairman.

I just wanted to clarify that we don't have issues with studying the babies who are stillborn or miscarried due to the microcephaly and Zika, and that is happening. But it is another thing entirely to have parents abort and use the aborted babies for research.

So, Ms. Schmainda, can information about microcephaly associated with Zika be obtained using fetal tissue from affected babies that are miscarried or stillborn?

Dr. SCHMAINDA. Yes, absolutely. And I think when we speak of abortions, induced abortions and the tissue we get from them as a reference or as a gold standard, that is completely incorrect because the identity, the genetic identity of these children are not known.

Mrs. HARTZLER. Very good. I would like to carry on some more questions with you.

Could you describe in detail how the tissue procurement process takes place, what personnel and equipment are involved?

Dr. SCHMAINDA. Absolutely. So, as I had mentioned briefly before, we actually have a full-time person that oversees a tissue bank. And they are on-call with a pager so they know when the tissue is going to be removed at the time of surgery. So, they have to be there within 30 minutes, carrying with them a liquid nitrogen Dewar because the tissue has be flash-frozen in order to maintain the quality of the research tissue. Otherwise, a lot of the analysis,

the advanced analysis like genetic and proteomic analysis, could not be performed with any reliability.

Mrs. HARTZLER. Are you familiar with how fetal tissue is procured, though, and the process involved with that?

Dr. SCHMAINDA. I am not, but I can't imagine it is any different.

Mrs. HARTZLER. If we could put up Exhibit A–2, this is the exact compensation chart for a procurement technician. And I think America needs to be aware of this process. They are paid $10 per hour plus a per-tissue or blood bonus as outlined in the table below. The tissue is divided up into categories A, B, and C. One to 10 specimens, for instance, of category A is $35 a tissue, and it goes up from there, $45 to $55, $65, $75 a tissue. So, there is a financial incentive for them to take this tissue, and they are getting paid for that.

And yet, if you could put up Exhibit A–3, we have, once again, the consent form that is given to the woman who comes in to have an abortion in a very, very stressful time in their life. We have already discussed how this form is clearly unethical because it makes promises to the woman saying that this is going to result in cures and has resulted in cures for AIDS, cancer, Alzheimer's, et cetera, which is totally false. So, women are already being told inaccurate information in order to induce them. And then it also says, "I understand I will not be paid." So my question is, how come the woman isn't paid for this?

Dr. SCHMAINDA. That is a good question because in all other—we look at coercion of the patient is a very, very severe, very strict guideline when you are putting the IRB together. So, we can never promise that there is any benefit to the patient when they undergo an IRB-approved study. And so having this information about diseases that is untrue and not talking about what could happen as the possible risks is also completely irregular, compared to——

Mrs. HARTZLER. Didn't you, in your testimony, give an example of some money that was spent by a procurement company for a sample? I am trying to find it. Do you remember it?

Dr. SCHMAINDA. Yes, $830 per fetal liver tissue sample.

Mrs. HARTZLER. So, a woman is not given any money for this. She is being coerced to sign this under duress with inaccurate information, and yet the procurement company is getting up to $830-some per liver, in addition to whatever else is in the sample. It could be people are getting rich off of this, and yet the woman is getting nothing from it, other than having an abortion.

I think it is just unconscionable that we would accept, as America, that this would continue on, when women are being taken advantage of and money is being made off of them at the expense of not only that woman but her aborted baby.

I yield back.

Mrs. BLACKBURN. The gentlelady yields back.

Mrs. Watson Coleman, you are recognized for 5 minutes.

Mrs. WATSON COLEMAN. Thank you, Madam Chairman. I wanted to ask Mr. Goldstein a couple of questions.

Mr. Goldstein, you mentioned that some promising research with regard to MS was stopped or has been negatively impacted. Could you please elaborate a little bit on what you mean, and what direction was it going into, and why it has not yielded that?

Dr. GOLDSTEIN. It was getting close to the clinical trial stage and then, as a result of the political discussion and the threats to abortion providers, it is believed that they stopped being willing to provide tissue any longer.

Mrs. WATSON COLEMAN. Dr. Goldstein, have there been cures to any diseases resulting from the research emanating from fetal tissue? Have any cures been found of anything?

Dr. GOLDSTEIN. I think we have gone back and forth on the vaccine issue a number of times. So, I think we will leave that one alone for the time being.

I think I am in the business of moving forward. I look for therapies for diseases where we don't yet have any. I am not aware of any that have definitely been solved using fetal tissue, although, arguably, the development of treatments for HIV depended a great deal on being able to develop humanized mice that had a human immune system in animals and I think that was initiated using fetal blood-forming stem cells.

Mrs. WATSON COLEMAN. Do you believe that anything on that form is creating an undue hardship or an intimidation or a misrepresentation to women who are being asked to consider whether or not they will donate this tissue?

Dr. GOLDSTEIN. I am sorry, which form?

Mrs. WATSON COLEMAN. The form that my colleagues keep referring to that says that women who are under duress need to sign in order to give their consent.

Dr. GOLDSTEIN. So, if it is the form that says therapies for diseases such as Alzheimer's disease and all the rest have already been found, I agree, that is an inappropriate statement and it should not have been made on that form. I don't know who wrote it. That would not have made it past my IRB, either.

Mrs. WATSON COLEMAN. It seems to me that this has been an interesting day where we have had empirical evidence as to the worthwhile use of fetal tissue research, that it has produced and is producing results moving us in the right direction to be cures and appropriate therapies and treatments for diseases and for injuries that otherwise negatively impact the life and the quality of life for individuals. It is also clear to me today that the question before us is just really nothing more than a proxy for getting at an attack on women's right to what has already been established as a safe abortion in this country. And it just concerns me that we would have a panel of legislators sharing misinformation and sharing information that isn't documented in any way, shape, or form, indicating that people are making money off of women's bodies and that there is something about people becoming rich by engaging in fetal tissue research and leaving it out there as if it is the truth when, in fact, we know it is not.

Mr. Goldstein, Dr. Goldstein, I know that you don't generally handle that end of it, but to your knowledge, is there an industry that is getting rich and that is taking advantage of women's body parts as a result of fetal tissue research?

Dr. GOLDSTEIN. Not to my knowledge.

Mrs. WATSON COLEMAN. Thank you. I yield back.

Mrs. BLACKBURN. The gentlelady yields back.

Mrs. Love, you are recognized for 5 minutes.

Mrs. LOVE. Thank you.

Dr. Lee, can you explain to me how organ donations are done at Georgetown Medical? What kind of codes of conduct must be followed in order to get consent for organ donation?

Dr. LEE. Well, I am not at Georgetown, but at Mercy Hospital in Pittsburgh, there is a consent form that is very detailed and the donation team is separate from any of the doctors who treat the patient and there has to be a fully informed consent there. And that complete separation—the doctors say, well, the team will come in and they want to talk to you, but they won't—the doctors who are treating the patient will not bring it up with the families.

Mrs. LOVE. OK. So, is there any contact between the person giving consent, the recipient of the organ, the technician that is transferring the organ, or the physician that is procuring the organ during or before the forms are signed or consent is given?

Dr. LEE. There is not direct—there might be—there is contact between the team that mediates between the procurement——

Mrs. LOVE. So, there is a mediator.

Dr. LEE. Yes, and that team is the one that speaks to the family members and patients. But there is always that go-between, that mediation.

Mrs. LOVE. Great. I want to focus, again, on trying to protect the minor.

Is it possible, Dr. Schmainda—did I get that——

Dr. SCHMAINDA. Schmainda.

Mrs. LOVE. Thank you. Is it possible for a minor undergoing an abortion procedure to be faced with the decision to donate tissue on the same day that she is receiving that procedure?

Dr. SCHMAINDA. That is unconscionable, no. At that age, no, that should never happen.

Mrs. LOVE. Does that happen?

Dr. SCHMAINDA. I am not aware. I mean, I am not in that industry, so I am not aware of exactly the procedures followed.

Mrs. LOVE. Does anyone know, on this panel, if that actually happens the day that the minor is receiving or the day that anybody is receiving the procedure, that they are faced with donating the tissue on that very day?

Dr. LEE. I don't think so. I don't think so—except for abortion, I think it is.

Mrs. LOVE. OK. So, from what I understand there are strict codes of conduct and guidelines for adult organ donations, but there are little to no laws or guidelines protecting minors when giving consent to perform an abortion or giving consent to have a child's tissue donated. Again, I am coming at this looking at my 14-year-old and seeing what it was like for her to have an ACL surgery and how frightened she was. I couldn't imagine a 14-year-old going into a clinic without someone there that she trusts, that is an advocate for her when she is faced with donating tissue of an organ when she is going to be receiving these procedures herself. I couldn't imagine doing that myself, let alone a minor.

I am trying to ask who is there to actually protect that minor when they are going in to have these procedures. Who is there on her side?

The last thing I want to say is that there are times in our history in this country that we thought the behavior and the terrible treatment of some human beings were OK. Throughout our history, we had the opportunity to look back and say we were wrong. I am here because we have looked back at behavior that we thought was unethical and we changed it. Boy, I hope that we live in a country where we can look at the history and say the treatment of an unborn child is unethical, the treatment of a minor that is going in to receive some of these procedures should have someone on their side, and I hope that we live in a country where we can look back and we can change some of those things.

I would not be here if we didn't have people making that courageous decision. I hope that we, in this country, are able to stand up and say the treatment is unethical, we are going to change it.

I yield back.

Mrs. BLACKBURN. The gentlelady yields back.

Mr. Nadler for 5 minutes.

Mr. NADLER. Thank you, Madam Chair.

Let me first make an observation. Dr. Lee, in his written testimony, says "there is a serious problem concerning the woman's consent regarding the use of tissues and organs from the abortion procedure. How can her consent have ethical or legal significance, given her previous choice to abort?" We went through this in the first panel, too.

He also said a little later, "Anyone with a just moral outlook would not consent to an abortion." Anyone with a just a moral outlook would not consent to an abortion; that is his opinion. That is the opinion of a lot people in this room, but it is not the opinion of a lot of other people. "How can her consent have ethical or legal significance, given her previous choice to abort?" Maybe the choice to abort had more significant questions. Maybe the fetus had Down Syndrome, for instance, and it is a less easy question.

There are plenty of religious leaders in this country who disagree with your moral conclusion. This is a moral question. It is a moral choice that is quite clearly debatable. It is not self-evident. It is clearly debatable since we have been debating it for the last 50 or 60 years without a conclusion. Even if individuals, such as two of our panelists and some others on this panel, may have moral opinions of which they are certain, other people have contrary opinions of which they are certain.

So, to say that because the woman, the mother, disagrees with your personal conclusion or the personal moral view of some church, therefore, you will take away—we should take away her moral right to make the choice on donation of fetal tissue, is an assertion of absolute moral arrogance which you have no right to make and we have no right to make. It is her decision, not ours, and not yours. And it is her moral decision, not ours, and not yours.

Second, I would like to ask Dr. Schmainda, I hope is correct.

Dr. SCHMAINDA. Schmainda.

Mr. NADLER. Dr. Schmainda, we have all agreed that the use of fetal tissue derived not from an abortion is ethical. The question is the use of fetal tissue derived from an abortion. And you said that the use of such tissue to cure, if it were possible, or perhaps

when it is possible, to cure Parkinson's or Alzheimer's, would create a market for lots of fetal tissue, since a lot of fetal tissue would be necessary to cure the Alzheimer's and the Parkinson's and, therefore, this should be avoided. But it is true that abortions in order to generate fetal tissue are absolutely illegal, and no one has suggested otherwise.

So, I gather—tell me if I am wrong—that you would rather have people suffer from curable diseases, you think it is more moral to have people suffer from Alzheimer's who could be cured, suffer from Parkinson's who could be cured, rather than use fetal tissue from abortions that would occur anyway, tissue that would otherwise be discarded. You would make the moral choice and you would impose it on society that those people should suffer from the diseases, if they were curable. Am I correct?

Dr. SCHMAINDA. The ends never justifies the means. You can't extinguish one life to save another.

Mr. NADLER. So, the answer is yes, you would because the ends don't justify the means. And the ends here, which is to cure people of diseases, don't justify the moral wrong of using tissue from an abortion that was not performed for this purpose—but tissue that would otherwise be thrown out—and you would rather have people suffering the disease. OK, we have a disagreement, and it is a very clear moral disagreement. And I hope you will not try to impose your moral view on the rest of us.

Third, everyone—I shouldn't say everyone. There have been a number of questions asked about the consent form to donate tissues. Are any of you in clinic settings where such consents might be sought, Dr. Lee, Dr. Schmainda, Dr. Goldstein?

Dr. SCHMAINDA. Yes.

Mr. NADLER. You are?

Dr. LEE. Which kind of consents are you talking about? You mean for fetal tissue?

Mr. NADLER. Yes.

Dr. LEE. Fetal tissue from abortions?

Mr. NADLER. Yes, fetal tissue from a specific abortion to be used for research or whatever.

Dr. SCHMAINDA. No, consents for research, for human research.

Dr. LEE. No.

Mr. NADLER. You are not. OK. So, you are not there. You don't really see what is going on. Sort of a red herring, because what I think some of the members of this panel are really concerned about is the underlying abortion decision, not the separate donation decision. I think you are concerned about that because you said abortion is always morally wrong and the mother should be—any mother who is so morally depraved as to consent to an abortion should be deprived of the right to consent to donating fetal tissue.

Dr. LEE. The basis for that—my argument was not that she was depraved because she was making a depraved decision——

Mr. NADLER. Sure it was.

Dr. LEE [continuing]. But because she was—no, that was not my argument. My argument was that she lacks the authority to make the decision because the authority to make a decision for your child is based on your having the interest of that child at heart.

Mr. NADLER. Therefore, because of your——

Dr. LEE. Someone who chooses to have her aborted no longer has——

Mr. NADLER. Reclaiming my time, which is going to run out. Because of your moral decision, you would take that right away from her for the reasons you or I stated in different form.

And yet at Planned Parenthood, going back to my question, I know that at Planned Parenthood, only after providing consent for abortion is the patient given the option for tissue donation. Tissue procurement personnel are trained to obtain informed consent for tissue donation only after the patient has consented to the abortion procedure. There is no evidence whatsoever—is anybody aware of any evidence that any donors of fetal tissue have ever felt coerced? That is my last question. Is anyone aware of any such——

Mrs. BLACKBURN. The gentleman's time has expired.

Dr. LEE. I would say that the general knowledge that these things are used for these could tilt the scale in favor of that decision.

Mr. NADLER. But you are aware of no coercion or——

Mrs. BLACKBURN. The gentleman's time has expired.

Mr. NADLER. Thank you.

Mrs. BLACKBURN. Mr. Duffy for 5 minutes.

Mr. DUFFY. Thank you, Madam Chair. I want to ask to have Exhibit A–1, –92, and –93 put up. And I want to go to Exhibit A–2 for the panel.

And maybe before I get there, Dr. Goldstein, you have to imagine what an aborted baby looks like when it comes out. Do you know how long it takes to carve out a little baby heart, or a little baby lung, or a little baby lung, or to take a little baby head? Do you know how long it takes?

Dr. GOLDSTEIN. I have no knowledge of that.

Mr. DUFFY. You are a doctor, though, correct?

Dr. GOLDSTEIN. I am a Ph.D.

Mr. DUFFY. Ph.D., OK. Any——

Dr. GOLDSTEIN. I am a scientist, not a physician.

Mr. DUFFY. Any idea? Well, to the panel, anyone know how long that would take? No.

From those I have asked, it doesn't take very long. It happens pretty quickly.

And so, on the moral/ethical conversation, usually as we look at economies, the more you produce, the cheaper something becomes. You become more proficient at it. But if you look at the pay scale—and by the way, let's be clear what this is. We have the procurement business that sends in a technician, one of their employees, into the abortion facility, implanted, embedded in the facility, that is looking at women who are coming through the facility and going out and getting consent to harvest these little baby lungs, little baby hearts, little baby heads. Does it seem odd to you that the cost of procurement when you go from 10 to 11, the cost doesn't get cheaper, the cost or the payment gets more for the technician. The technician gets more money the more that they produce. Does that seem odd to you, if profit motive is not an element of this business?

Dr. Goldstein, does that seem strange?

Dr. GOLDSTEIN. I have no basis on which to judge that. I can barely see the exhibit.

Mr. DUFFY. Well, I think it is in front of you. Open up your little packet. I think it is right there.

Dr. GOLDSTEIN. Nope.

Mr. DUFFY. I am asking you to use your common sense. You don't have to be a Ph.D.

Dr. GOLDSTEIN. I am honestly—I am not going to speculate about something that I don't have firsthand knowledge of.

Mr. DUFFY. Let's talk about firsthand knowledge, because you are obviously in the business and promoting the use of fetal tissue. And I think you earlier indicated that you would agree with the law that we shouldn't make a profit—profit shouldn't be made off the sale of little baby body parts, right? Is that your testimony?

Dr. GOLDSTEIN. So, that has its roots, as I understand it, in the Uniform Anatomical Gift Act.

Mr. DUFFY. Do you agree with it? Do you agree with the fact that we shouldn't profit off of the sale of baby body parts?

Dr. GOLDSTEIN. Yes.

Mr. DUFFY. OK. And so what work have you done to make sure, I think it was Neuralstem, doesn't make a profit off of the baby body parts that they receive from clinics or they don't pay clinics for the body parts that they receive? Do you do any research into that?

Dr. GOLDSTEIN. I have asked them if they complied with the law. They have told me they complied with the law.

Mr. DUFFY. So, that is it?

Dr. GOLDSTEIN. Just as you trust the man sitting next to you to comply with the law——

Mr. DUFFY. I don't trust Mr. Harris.

But that is all you have done. You haven't taken any further steps?

Dr. GOLDSTEIN. I am in no position to actually launch an inquiry like that. I don't have investigative powers the way the Congress does.

Mr. DUFFY. So, you would agree that Congress should use its investigative powers to look into this issue.

Dr. GOLDSTEIN. No, I don't. I honestly think that Congress has better things to do with its time.

Mr. DUFFY. And we should just take on blind faith. You get a specimen. How much do you pay for a specimen? A little line, what do you pay for it?

Dr. GOLDSTEIN. The material we get from Neuralstem is provided under a collaboration.

Mr. DUFFY. How much do you pay?

Dr. GOLDSTEIN. We don't pay them anything for it.

Mr. DUFFY. They give it to you for free?

Dr. GOLDSTEIN. It is part of the whole cost of doing the clinical trial. So, we pick up part of the cost of the clinical trial in doing the surgery; they pick up part of the cost; they provide the cells.

Mr. DUFFY. So, there is no financial incentive. They are just a pure middle man. They don't make any money on this. Is that your position, Dr. Goldstein?

Dr. GOLDSTEIN. I would be surprised if they didn't have a financial incentive. They are a publicly held company. They are required

by law to have a profit motive. I don't know the details of how they carve out, where they generate profit, where they don't.

Mr. DUFFY. You just told me that you agree with the law that they shouldn't make a profit, but then you assume that they are making a profit.

Dr. GOLDSTEIN. They are growing cell lines, which are derived from fetal origin. It is not the fetal tissue itself. The NIH recognizes a distinction between established cell lines and fetal tissue itself.

Mr. DUFFY. So, here we have an incentive to procure more specimens and get more money for those specimens. I think that calls into question a need to look a little deeper.

Quickly, do you think, Dr. Goldstein, that we should be using this research, as Ms. Charo would say, for taste testing and cosmetics?

Dr. GOLDSTEIN. I think the issue of cosmetics was adequately addressed by Representative Speier, I believe it was, a few moments ago, where treatment for burns is an adequate and appropriate cosmetic reason.

Mr. DUFFY. Don't you then think that in the sheet where we are going to get consent that we should say this is not life-saving, this is for taste tests or this is for cosmetics?

Mrs. BLACKBURN. The gentleman's time has expired.

Mr. DUFFY. I yield back.

Mrs. BLACKBURN. The gentleman yields back.

I will reclaim my 5 minutes and wrap this up. You all have been patient with us.

As we look at the bioethics of this situation, Dr. Schmainda, what I have seen is a difference of opinion between some of those on whether fetal tissue is necessary, it is a convenience, or it is a cost-saving. So, can you kind of help us understand how that difference of opinion exists?

Dr. SCHMAINDA. Absolutely. I think the issue of researchers using fetal tissue is largely overexaggerated. There is $76 million from the NIH given to those that use fetal body parts for their research. That is out of an annual budget of $30 billion, that amounts to 2.5 percent. Also, there are maybe 160 investigators funded by the NIH. There are 300,000 investigators, overall, funded by the NIH. So, this is not going to change the direction of science.

Just two days ago, I looked at PubMed, which is the area you look for the most recent scientific—or all the scientific—publications. There are over 32,000 articles on adult stem cell therapy, and rarely ever do you get to publish anything with a negative result. I think that science will probably be better without it, because whenever we do have limitations on both sides of the panel, we say when you have a problem you typically—I completely agree in the creativity of the scientific mind to overcome these challenges. And I think we will—I know we will come up with alternatives.

Mrs. BLACKBURN. Let me ask you one more thing. There has been a question about the immunized mice. Can't that come from adult stem cells?

Dr. SCHMAINDA. You know, I can't speak to specific things, but what I know from colleagues of mine doing immunology research,

as they say, it is not essential. It has given them nothing more than what they already get from adult stem cell models.

Mrs. BLACKBURN. All right, I want to go back to—and I am going to come to you, Dr. Lee. Go back to Exhibit A–3, but let's go a little bit further down this permission form. Do you have the permission form in front of you?

Dr. LEE. I don't.

Mrs. BLACKBURN. OK. If someone will be sure that these are at the desk or, Ms. Schmainda, if you have one, if you will share.

Dr. LEE. OK.

Mrs. BLACKBURN. As you look at Exhibit A–3, and we have talked about the statement at the top of that permission form that is misleading. Go a little further down. It says, "I understand I have no control over who will get the donated blood and/or the tissue or what it can be used for." And then a little further down: "I understand there will be no changes to how or when my abortion is done in order to get my blood or the tissue." And the next one: "I understand I will not be paid."

Now, as we look at this, I would like to hear from you, Dr. Lee, because we have heard about how quickly the tissue has to be pulled. Dr. Schmainda talked about this, of how they have someone so close at hand within those first few minutes, and then the tissue is properly treated and moved on for the research that they are going to go. Do you think this is a proper representation to women who are going in for an abortion who don't understand that there is a profit motive or a financial motive behind this, when you look at Form A–2 that shows what they are being paid, and then they are asked to say and agree that they have no control over their donated blood or tissue and that there will be no changes or manipulations on that abortion or how it is done and the time that it is done? And that there is no financial compensation to them?

I would like to hear your take on the ethics of the situation with these items on that form.

Dr. LEE. Well, it seems to me that there is an effort to present this in, I would say, a sanitized manner. It sounds like everything is being done altruistically and that no one here is making any money off of this. And I think when you talk about someone who is there, working on site, who gets compensated more the more parts are received, it makes it incredible to think that no one is really profiting from these things or is getting paid.

So, I think that raises questions about the accuracy of the representation about this all being—that there is no profit motive involved, that there is no—that it is always just completely altruistic.

Also, I think it is good to note that all of this is at a time when presented to them, when I think knowing that this is something that might come up or that is done, that fetal tissue is so-called donated, that can tilt the scale, I think in her decision.

So, I don't think it is credible to say that——

Mrs. BLACKBURN. My time has expired, and I would ask you to wrap up. I thank you for the answer to the question.

I would like to remind all members that they have 10 business days to submit questions for the record and I ask the witnesses to respond to the questions very promptly. I know we are all going to

have questions for writing. Members should submit those questions by the close of business on March 16th.

Mr. HARRIS. Madam Chair, I move to enter into the record 10 articles regarding nonfetal sources to treat some of the neural and renal diseases we have discussed here today. The minority has been provided with copies.

[The information appears at the conclusion of the hearing.]

Mrs. BLACKBURN. Without objection, so moved.

Ms. SCHAKOWSKY. Madam Chair, I would like to have submitted to the record the documents that have already been approved by the majority.

[The information appears at the conclusion of the hearing.]

Mrs. BLACKBURN. Absolutely. So ordered.

We thank our witnesses. And yes, we are going to submit for the record the exhibits that we have used today.

[The information appears at the conclusion of the hearing.]

Mrs. BLACKBURN. Without objection, so ordered.

And without objection, the subcommittee is adjourned.

[Whereupon, at 1:43 p.m., the panel was adjourned.]

[Material submitted for inclusion in the record follows:]

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON ENERGY AND COMMERCE

February 29, 2016

TO: Members, Select Investigative Panel

FROM: Panel Majority Staff

RE: Hearing on "Bioethics and Fetal Tissue"

On Wednesday, March 2, 2016, at 10:00 a.m. in HVC-210, the Select Investigative Panel will hold a hearing entitled "Bioethics and Fetal Tissue." The hearing will focus upon ethical issues raised as a result of information recently made public about fetal tissue donations, transfer of fetal tissue, and use of fetal tissue by research institutions. The witnesses will provide testimony relating to their respective fields of philosophy, clinical practice, medical research, and law.

Each perspective will help the Panel understand the ethical questions, both at a theoretical level and a practical level, that arise when fetal tissue is acquired and used in biomedical research.

BACKGROUND

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion service providers and the business practices of the procurement organizations who sell fetal tissue. This Panel centralized the investigations that were already being conducted by the Committees on Energy and Commerce, Judiciary, and Oversight and Government Reform by bringing them primarily under one umbrella.

A. History of Ethical Discussion about Bioethics

Bioethies has its origins as a field of academic inquiry in the early 1960s due to extraordinary advances and development in American medical knowledge and practice: organ transplantation, kidney dialysis, respirators, and intensive care units (ICUs) made possible medical procedures never before imagined. The first heart transplant raised ethical questions relating to the sources of organs for transplantation, how they would be allocated, and payment for these procedures.

Public debates took place and, in response, scholars and academics began to think and write about these issues, and scholars began to fuse theoretical ethics with applied or practical ethics. Since that era, continuing biomedical advances have presented bioethical questions that need to be confronted and addressed by societies..

B. Governmental Involvement in Bioethics[1]

The Presidential Commission for the Study of Bioethical Issues continues the nearly 40-year history of groups established by the president or Congress to provide expert advice on topics related to bioethics. These groups have differed in their composition, methods, and areas of focus, but they have shared a common commitment to the careful examination and analysis of ethical considerations that underlie our nation's activities in science, medicine, and technology.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78) is generally viewed as the first national bioethics commission. Established by the 1974 National Research Act, the National Commission is best known for the Belmont Report.[2] It identified fundamental principles for research involving human volunteers and was the basis of subsequent federal regulation in this area.

The Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1978-83), also established by Congress, produced reports on foregoing life-sustaining treatment and access to health care, among other topics. Its 1981 report *Defining Death* was the basis of the Uniform Determination of Death Act[3], a model law that was enacted by most U.S. states.

The Advisory Committee on Human Radiation Experiments (1994-95) was created by President Bill Clinton to investigate human radiation experiments conducted from 1944 -1974 as well as radiation intentionally released into the environment for research purposes. The committee considered the ethical and scientific standards for evaluating these events and provided recommendations aimed at ensuring that similar events could not be repeated.

Since the mid-1990s, each of the past three presidents has established bioethics commissions to explore ethical issues in science, medicine, and technology. The National Bioethics Advisory Commission (1996-2001), created by President Clinton, examined topics including cloning, human stem cell research, and research involving human subjects. President George W. Bush established the President's Council on Bioethics (2001-2009), which issued reports on stem cell research, human enhancement, and reproductive technologies, among other

[1] http://bioethics.gov/history, From the Presidential Commission Website.

[2] www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

[3] http://uniformlaws.org/ActSummary.aspx?title=Determination%20of%20Death%20Act

subjects. President Barack Obama created the current commission by Executive Order in November 2009.

I. WITNESSES

- **Paige Comstock Cunningham, JD,** is the executive director of The Center for Bioethics & Human Dignity. She is a Fellow at the Institute for Biotechnology and the Human Future, and a Trustee of Taylor University. Cunningham is an adjunct professor of law at Trinity Law School and Trinity Graduate School. Cunningham lectures regularly and has published numerous articles, editorials, and book chapters in the areas of law, bioethics, and public policy. .

- **Patrick Lee, Ph.D.,** is the John N. and Jamie D. McAleer Professor of Bioethics and the director of the Center for Bioethics at Franciscan University of Steubenville. He is known nationally as a keynote speaker and author on contemporary ethics, especially on marriage and the value of human life. He has published over 40 articles in refereed journals or books..

  Gerard Kevin Donovan, MD, MA, is Senior Clinical Scholar at the Kennedy Institute of Ethics at Georgetown University. He is also Director of the Pellegrino Center for Clinical Bioethics, and Professor of Pediatrics at Georgetown. Dr. Donovan was the founding Director of the Oklahoma Bioethics Center and has three decades of experience in clinical bioethics and clinical medicine being recognized as one of America's "Best Doctors." He has served on multiple ethics committees for hospitals and national organizations as well as chairing an Institutional Review Board.

- **Kathleen M. Schmainda, Ph.D.** is Professor of Radiology and Professor of Biophysics at the Center for Imaging Research at the Medical College of Wisconsin. She received her Ph.D. in Medical Engineering from Harvard-MIT, and completed her Postdoctoral Fellowship in MRI at Massachusetts General Hospital. .

- **R. Alta Charo, J.D.** is the Warren P. Knowles Professor of Law and Bioethics at the University of Wisconsin at Madison, where she is on the faculty of the Law School and the Department of Medical History and Bioethics at the medical school. Professor Charo has authored or contributed to over 100 articles, book chapters and government reports on law and policy related to environmental protection, reproductive health, new reproductive technologies, medical genetics, stem cell research, science funding, and research ethics. She has served as a member of numerous boards, including the Alan Guttmacher Institute, the Foundation for Genetic Medicine, and the National Medical Advisory Committee of the Planned Parenthood Federation of America.

- **Lawrence S.B. Goldstein, Ph.D.** is Distinguished Professor, Department. of Cellular and Molecular Medicine, Department of Neurosciences at the University of California, San Diego School of Medicine. He is also the Director of the UC San Diego Stem Cell Program, the Scientific Director of the Sanford Consortium for Regenerative Medicine, and the Director of the Stanford Stem Cell Clinical Center. Dr. Goldstein's research focus areas include genetics and genomics, membrane trafficking, neurodevelopment and neurodegenerative disease, and stem cell biology. Dr. Goldstein received his Ph.D. in genetics from the University of Washington, Seattle. He was the Leob Chair in Natural Sciences at Harvard University, and has received several awards.

II. ISSUES

A. Today's Bioethical Questions

Today's headlines are full of announcements and predictions that a few short years ago were the subject of speculative fiction. Organ reconstitution, three child parents, personalized medicine, organ cloning, chimeras, gene therapy and editing, and bioinformatics are all recent advances that the public has come to learn and understand. The current director of the National Institutes of Health has proposed compiling DNA information to help inform medical decisions and therapies. While these therapies further knowledge biomedical and scientific information related to medical treatments and therapies, they also present broader ethical questions."

B. The following issues may be examined at the hearing:

- Does fetal tissue research violate human dignity?
- Should fetal tissue be grown for the purpose of transplant?
- Should anyone profit from fetal tissue? Why not?
- What level of disclosure should a patient have before an abortion? Before a donation of tissue?
- Should an abortion clinic have equipment and expertise for perinatal care for children born alive?
- Who should obtain the fetal tissue donation consent?

III. STAFF CONTACTS

If you have any questions regarding this hearing, please contact March Bell or Rachel Collins of the Committee staff at (202) 225-2927.

SELECT INVESTIGATIVE PANEL OF
THE COMMITTEE ON ENERGY AND COMMERCE –
114TH CONGRESS
ROLL CALL VOTE # 1

MOTION: Motion by Mr. Pitts to table the motion to quash subpoenas offered by Mr. Nadler.

DISPOSITION: **AGREED TO**, by a roll call vote of 8 yeas and 6 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mrs. Blackburn	X			Ms. Schakowsky		X	
Mr. Pitts	X			Mr. Nadler		X	
Mrs. Black	X			Ms. DeGette		X	
Mr. Bucshon	X			Ms. Speier		X	
Mr. Duffy	X			Ms. DelBene		X	
Mr. Harris	X			Mrs. Watson Coleman		X	
Mrs. Hartzler	X						
Mrs. Love	X						

03/02/2016

The Washington Post

The Post's View

The Planned Parenthood witch hunt

By Editorial Board February 20

TWELVE STATES that undertook investigations of Planned Parenthood found no wrongdoing. An additional eight states refused even to investigate, citing lack of credible evidence. A grand jury in Texas and a federal judge in California exonerated the organization after each conducted extensive reviews. Three congressional committees failed to turn up any improprieties. In short, the hidden-camera videos purporting to show illegal selling of fetal tissue show no such thing.

Despite all that, a Republican-led House panel is undeterred in conducting its own investigation, or, more accurately, witch hunt. Even more troubling than the considerable time and money that will be wasted is the potential damage to health care and medical research.

The coyly named Select Investigative Panel on Infant Lives has made sweeping requests (including three subpoenas) for documents and information from more than 30 agencies and organizations that provide abortions or are involved in fetal tissue research. Of particular concern is the panel's demand for the names of doctors, medical students and researchers involved in performing abortions or conducting research with fetal tissue. Democrats on the panel decried the creation of such a database, which — without rules to protect it from public disclosure — risks individual privacy and safety without legitimate reason. How is the name of a graduate student who five years ago was an intern at a lab relevant to anything?

Rep. Marsha Blackburn (R-Tenn.), chair of the House panel, has defended the investigation as necessary because of lingering questions raised by secretly recorded videos of Planned Parenthood personnel released last year by the equally misnamed Center for Medical Progress. Those videos, supposedly showing Planned Parenthood illegally selling aborted fetal organs for profit, have been discredited. A grand jury empaneled in Houston to investigate Planned Parenthood ended up indicting the activists who produced the videos and, after reviewing the evidence for two months, cleared Planned Parenthood of any wrongdoing. U.S. District Court Judge William H. Orrick reached the same conclusion, granting a preliminary injunction prohibiting release of illegally obtained recordings and materials in a decision that laid bare the fraud against Planned Parenthood. Also noted by the judge was the alarming increase in incidents of harassment and violence directed against abortion providers since the videos were released

last July. Among them: four incidents of arson and the attack on a Colorado clinic by a gunman in which three people were killed.

Federal law permits medical use of fetal tissue. The handful of Planned Parenthood clinics in which patients are able to donate fetal tissue adhered to the law that allows reasonable payment for costs associated with donations, but they have stopped accepting any reimbursement because of the controversy. Congress, with approval from both sides of the aisle, legalized fetal tissue research in 1993 because of the potential for scientific advances in treating and curing illnesses.

Congress has the prerogative to change that law, if it wants to undermine the kind of medical research that has led to breakthroughs such as the polio vaccine. But it has no call to engage in a reckless investigation with the potential to cause a great deal of harm.

Read more on this topic:

The Post's View: Planned Parenthood has been absolved. The GOP should give up its crusade.

Dana Milbank: The GOP still has nothing to show for its anti-Planned Parenthood campaign

Cecile Richards: Planned Parenthood president: These extremist videos are nothing short of an attack on women

George F. Will: Planned Parenthood and the barbarity of America

Kathleen Parker: Premature finger-pointing after the Planned Parenthood shooting

BUSINESS / Michael Hiltzik

Planned Parenthood and the cynical attack on fetal tissue research

Supporters of Planned Parenthood rallied last month in Salt Lake City, where Utah Gov. Gary Herbert is aiming to stop disbursing federal money to the women's health organization. (Leah Hogsten / Associated Press)

By **Michael Hiltzik · Contact Reporter**
The Economy Hub

SEPTEMBER 4, 2015, 10:36 AM

As with all orchestrated uproars, the current political attack on Planned Parenthood employs distraction and misdirection to keep people from focusing attention on facts and reality. In this case, the distraction involves an attack on the use of fetal tissue in medical research, which may well become collateral damage in the campaign against Planned Parenthood.

If that happens, it would warrant our moral outrage. It's time to set the record straight.

The prominent bioethicist R. Alta Charo of the University of Wisconsin does so incisively in the current issue of the New England Journal of Medicine.

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"We have a duty to use fetal tissue for research and therapy," she writes. "And that duty includes taking advantage of avenues of hope for current and future patients, particularly if those avenues are being threatened by a purely political fight."

“

Abortion opponents have added millions of people to the collateral damage of the abortion war.

- Bioethicist R. Alta Charo

As Charo notes, the campaigu of distorted videos mounted against Planned Parenthood by the inaptly named Center for Medical Progress aims to depict fetal tissue research as the unholy beneficiary of induced ahortions. It's a convenient target, for there's no question that fetal tissue research exists, and that some of the tissue comes from abortions. But that's where the reality ends and the sophistry begins.

Charo walks us through the techniques and history of the attack. A key is to twist the language to distort the work, portraying it as "ghoulish vivisection and body-part snatching." (In an earlier op-ed for the Washington Post, she points out that the anti-abortion lobby uses such terms as "'harvest' (as opposed to 'recover')" to describe the process of obtaining the tissues, the hetter to depict the process as callous.

Yet what's commonly overlooked is the value of this research for medical science.

"Virtually every person in this country bas benefited from research using fetal tissue," Charo writes. "Every child who's been spared the risks and misery of chickenpox, ruhella, or polio can thank the Nobel Prize recipients and other scientists who used such tissue in research yielding the vaccines that protect us (and give even the unvaccinated the benefit of herd immunity). This work has been going on for nearly a century, and the vaccines it produced have been in use nearly as long. Any discussion of the etbics of fetal tissue research must begin with its unimpeachable claim to have saved the lives and health of millions of people."

Members of the anti-abortion lobby "have overwhelmingly partaken of the vaccines and treatments derived from fetal tissue research and give no indication that they will forswear further benefits. Fairness and reciprocity alone would suggest they have a duty to support the work, or at least not to thwart it."

Some history is instructive here. This is not the first time that an attack on fetal tissue research has been used as a wedge against abortion rights. The same thing happened after the Supreme Court's 1973 decision in Roe v. Wade. "Right-to-life leaders seized upon fetal research as an issue," wrote Rachel Benson Gold of the Alan Guttmacher Institute in 1989, "arguing that using fetal tissue obtained from

induced abortions...was an extension of a so-called 'abortion mentality' that 'dehumanized' the fetus."

Their campaign deeply politicized the research, as may well happen today. What followed was a series of federal moratoriums in 1974-75 and 1988-93, each one ending after a blue-ribbon advisory committee judged the research morally defensible and recommended safeguards.

The most important committee was convened by the National Institutes of Health in 1988, during the Reagan administration. The panel included several abortion opponents, including its chairman, retired U.S. Judge Arlin M. Adams of Philadelphia, but nevertheless voted overwhelmingly in favor of allowing fetal tissue research, with appropriate conditions.

These were, chiefly, that the decision by a woman to donate the tissue of an aborted fetus remain separate from, and subsequent to, the decision to undergo the abortion; that tissue donations for transplantation into specific persons, including family members, be harred; and that no payments be allowed beyond the recovery of costs.

These rules are still in place. And despite the efforts of Center for Medical Progress' agents to coax or goad Planned Parenthood officials into flouting them on videotape, their targets upheld those principles at every step. And that's on videotape.

One big concern of the 1988 panelists was whether the prospect of donating tissue for medical research would induce women who might not otherwise choose abortion to do so. There was absolutely no evidence tbat this had happened in the past. Commission member John D. Robertson, a University of Texas law professor, called it a "hypothetical fear." He wrote: "The panel heard no convincing evidence that a pregnant woman's decision against abortion would be changed by the prospect of anonymous tissue donation." The recommended safeguards, he added, would make that prospect even more remote.

Nevertheless, he continued, "opponents would ban all federally supported fetal tissue research... out of the hypothetical fear, which the Panel has rejected, that abortions will increase."

Yet fetal tissue research remained politicized for years more. Interestingly, the effort to overturn the moratorium was bipartisan, for many abortion foes in Congress viewed fetal tissue donations as "life-affirming"; in 1992, legislation to reverse the ban was pushed by GOP Sens. Bob Dole of Kansas and John Danforth of Missouri, among others.

Rep. Fred Upton, R-Mich -- one of the lawmakers who harassed Planned Parenthood partner StemExpress over the Center for Medical Progress' deceptive videos -- even went to the White House to talk President George H.W. Bush out of continuing the ban. It was finally ended by President Clinton, by executive order in 1993.

Fetal tissue research is once again in the political crosshairs, despite indisputable evidence that it saves lives.

"It seems clear that the needs of current and future patients outweigh what can only be symbolic or political gestures of concern," Charo writes. "Fetal tissue research has already led to investigational therapy for end-stage breast cancer and advances against cardiac causes, and transplantation research is actively being pursued for diabetes (using fetal pancreatic islet cells), amyotrophic lateral sclerosis (using neural fetal stem cells injected into the spine), and in a major European initiative, Parkinson's disease (using fetal dopamine cells)." The first polio vaccine was based on cultures of human fetal cells, which were also crucial factors in the development of the rubella vaccine, which helped to wipe out a disease that caused countless birth defects in the children of women infected during pregnancy.

The campaigners against Planned Parenthood, seeking nothing but a political pelt to hang on their wall, would place all such research at risk. "Abortion opponents have added millions of people to the collateral damage of the abortion war," Charo writes, calling it "a betrayal of the people whose lives could be saved by the research and a violation of that most fundamental duty of medicine and health policy, the duty of care."

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Informed Consent in Tissue Donation

Expectations and Realities

JANUARY 2001
OEI-01-00-00440

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EXECUTIVE SUMMARY

PURPOSE

To assess expectations for and limitations of informed consent for tissue donation.

BACKGROUND

Human tissue is an important source of medical treatment. The specific number of tissue donors in this country is unknown. It is clear, though, that the numbers are growing. In 1999, more than 20,000 donors provided cadaveric tissue, up from perhaps 6,000 donors in 1994. Tissue banks distributed over 750,000 allografts for transplantation in 1999.

A first step in tissue donation is obtaining consent from a deceased individual's family. Even if the individual had indicated willingness to donate organs (*e.g.*, on the driver's license), it is practice in this country to obtain consent from the next-of-kin.

Tissue banking is subject to more limited regulation than is the nation's organ procurement system, even though both organ procurement organizations (OPOs) and tissue banks are involved in approaching families to request consent for donation. For example, the National Organ Transplant Act requires OPOs to meet certain organizational and staffing requirements; the Act also requires OPOs to assist hospitals in establishing and implementing protocols for making routine inquiries about organ donation by potential donors. No similar requirements exist for tissue banks.

This report responds to a request from the Secretary of Health and Human Services, asking the Office of Inspector General to examine issues related to informed consent for tissue donation. We base our report on interviews with 30 organizations involved in tissue recovery and processing; responses from more than 50 donor families to questions posted on an Internet web site; interviews with officials of associations representing sectors of the tissue banking industry; and a review of laws, regulations, and association standards for tissue banking.

In this report, we use the term "tissue banks" to refer to entities involved in procuring, processing, storing, and distributing tissue. We use the term "tissue" to refer to skin, heart valves, and musculoskeletal tissue such as bone, cartilage, ligaments, and tendons.

FINDINGS

The expectations and altruistic motives of donor families are the foundation of tissue banking. Donor families and tissue bank staff told us that in agreeing to donation, families make some basic assumptions:

- **Enhancing the lives of others.** Tissue will be used to meet important medical needs.
- **Respect for the donor and the family.** The donor's body will be respected during tissue recovery, the gift will be recognized as coming from donated human tissue, and

the donor family's emotional needs will be respected.

- **Trust in the tissue banking community.** Organizations involved in procuring and using the donation will act as stewards of the gift.

However, the reality of tissue banking raises some underlying tension with families' assumptions.

- **Commercialization of tissue banking.** Large scale financial operations may overshadow the underlying altruistic nature of tissue donation.
- **Tissue viewed as a commodity.** After processing, tissue and products containing tissue often are marketed and sold as a medical supply, rather than as a donation.
- **Cosmetic uses of tissue.** Some tissue, particularly skin, may be processed into products that are used for cosmetic purposes that may not be medically indicated.

Fundamental factors limit the amount of information that is given to families.

- Families are asked to give their consent at a point in time when they are extremely vulnerable.
- Families may not wish to receive detailed information about tissue banking.
- Obtaining consent and documenting a donor's medical suitability require time-consuming and invasive questioning about a recently deceased loved one.

Current practices in requesting consent raise concerns about how and what information is provided to families.

- Tissue banks often request consent over the telephone, rather than in person.
- Many tissue banks rely on staff from other organizations to obtain consent. There may be little training and accountability of external tissue requestors.
- Tissue banks provide donor families with little written material at the time of donation.

Until recently, standards governing how families are approached and what they are told about tissue donation have been nonexistent. However, some advice and guidance have emerged.

- Federal laws and regulations do not address the manner in which tissue banks obtain consent.
- States' Uniform Anatomical Gift Acts do not address what information tissue banks should provide in obtaining consent.
- The National Donor Family Council has proposed key elements of an informed consent policy for tissue donation.
- Organizations representing the tissue banking industry have issued a statement that addresses elements of informed consent. These organizations include the American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations, and the Eye Bank Association of America. The AATB is incorporating this statement into its accreditation standards for tissue banks.

CONCLUSION

Tissue banking and processing practices have gradually diverged from donor families' expectations in recent years. The tissue banking industry has expanded and become more complex and costly. New ways of using tissue for medical treatment have been developed. Processed tissue often is marketed and sold like any other medical product. For some people, these practices call into question the non-profit basis of the tissue banking community. Despite these changes, the industry's foundation remains that of human tissue altruistically donated by individuals and their families at an extraordinarily sensitive time. The special nature of this product, and the circumstances under which it is made available, call for steps to be taken above and beyond those that would apply to most other business or philanthropic enterprises.

RECOMMENDATIONS

Importance of increasing donation. The Office of Inspector General has examined issues related to organ, tissue, and bone marrow donation, allocation, and transplantation for more than a decade. The principles underlying our work have focused consistently on enhancing equity for patients, improving access to transplantation, and encouraging donation.

Encouraging donation was of paramount importance to us as we developed our recommendations. It is our hope that these recommendations will encourage donation. Our recommendations encourage joint action among groups representing the tissue banking industry, donor families, and the government.

RECOMMENDATIONS TO THE DEPARTMENT

The Health Resources and Services Administration should work with groups representing donor families and the tissue banking industry to develop guidelines for conveying information to families about tissue donation.

HRSA's Division of Transplantation supports the development of programs to increase donation. In that role, HRSA has gained considerable expertise about effective practices in requesting consent. The agency could act as a resource to tissue banks and families.

HRSA's efforts could focus on such areas as:

- Identifying principles and guidelines that should underpin consent requests, such as those outlined recently by the National Donor Family Council and by industry groups;
- Making suggestions as to the type, format, and content of written information about donation that tissue banks could share with families.
- Making recommendations on information that would be useful for training tissue bank staff and external requestors; and
- Making recommendations on assessment tools that would be useful in evaluating the effectiveness of requestors.

The Health Care Financing Administration should address informed consent for tissue donation through the Medicare conditions of participation.

HCFA requires hospitals to assure that the family of each potential donor is aware of its options to donate tissues, organs, and eyes. Elsewhere in this report, we call upon donor family groups, the tissue banking industry, and HRSA to develop guidelines for conveying information to families about tissue donation. HCFA could use these guidelines as it provides information about the conditions of participation for organ, tissue, and eye donation. The agency could publicize these principles through the HCFA Internet site.

In the longer term, the agency may wish to examine the Medicare conditions of coverage governing organ procurement organizations. In that examination, the agency could consider additional requirements to strengthen working relationships between OPOs and tissue banks. Such requirements might include:

- Holding OPOs responsible for informed consent for tissue donor families when they request consent on behalf of tissue banks; and
- Requiring OPOs to include tissue banks in the training that they conduct for designated requestors.

RECOMMENDATIONS TO THE INDUSTRY

At the time of obtaining consent, tissue banks should provide families with written materials that provide fuller disclosure about the uses of tissue and the nature of the gift.

Tissue banks should give written material to families at the time the banks ask for consent to donation, or in the days immediately following the request. The material should be appropriately thorough. It would serve as one way to supplement the information that requestors provide to the family during their conversation about donation, while providing requestors with flexibility to adapt that conversation to the unique needs and responses of each donor family. At a minimum, this material should include:

- A copy of the signed consent form;
- Written material on how to follow up with the tissue bank if concerns arise;
- A full description of the uses to which donated tissue may be put; and
- A list and description of other companies and entities with which the bank has relationships for processing and distributing tissue.

Tissue processors and distributors should ensure that information accompanying their product clearly indicates it is derived from *donated* human tissue.

Such a step would require only minor changes in packaging and marketing materials. But it would go a long way towards showing ongoing respect for the donor, the family, and the gift of donation. Tissue banks should:

- Indicate clearly on all tissue packaging that the contents derive from donated human tissue; and

- Indicate clearly on all marketing and informational material that these products derive from donated human tissue.

Tissue banks should foster greater accountability for the performance of those who request consent for donation.

Responsibility for ensuring that requestors are providing accurate, sensitive, and appropriate information rests with tissue banks and the processors with which they work. These organizations should:

- Ensure that requestors — both from their own organizations and from hospitals — are fully and appropriately trained;
- Provide continuing education for requestors; and
- Conduct an ongoing assessment of requestor performance as a means of ensuring that they are providing full and accurate information to families approached for donation.

The tissue banking industry should work with groups representing donor families to explore a process for periodic public disclosure about tissue banks' financing.

The purpose of the examination we recommend here is to respond to family and general public concerns about knowing the sources of funding for tissue banks and other entities with which the bank has financial arrangements. The examination would consider whether financial information would be useful as part of a package of information provided to donor families. The examination would consider:

- What types and how much financial information would be useful for families and individuals in making decisions about donation;
- The advantages and disadvantages of disclosure, including the potential impact of financial disclosure on donation;
- Whether the information should be provided in all cases, or only if requested by a family; and
- The content, style, and format of disclosure.

COMMENTS ON THE REPORT

We received comments on a draft of this report from the Department of Health and Human Services. They are supportive of our findings and recommendations. The full text is included in Appendix C.

Our work in tissue banking continues. We will maintain an active watch on how the tissue banking community responds to the concerns we have raised.

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INTRODUCTION

PURPOSE

To assess expectations for and limitations of informed consent for tissue donation.

BACKGROUND

Transplantation of Human Tissue

Human tissue is an important resource used in medical treatment. Physicians and dentists use cadaveric human tissue for a variety of medical purposes. Donated skin can meet critical needs in healing burn victims and in reconstructive surgery. Donated bone can be implanted to replace cancerous bone, for knee and hip replacements, and for spinal surgery; it can be processed into powder for use in dental surgery. Donated heart valves can replace defective valves in young children, saving their lives.

The exact number of tissue donors in this country is unknown. It is clear, though, that the numbers are increasing. In 1999, more than 20,000 donors provided cadaveric tissue, up from perhaps 6,000 donors in 1994. Tissue banks distributed over 750,000 allografts for transplantation in 1999.

Consent for Donation

A first step in tissue donation is obtaining the consent of a deceased individual's family. Even if the individual had indicated willingness to donate organs and tissues (*e.g.*, on the driver's license), it is practice in this country to obtain consent from the next-of-kin. A family may refuse to give consent, or it may give consent for donation of all or only some tissues.

Tissue banking is subject to more limited regulation than the nation's organ procurement system, even though both organ procurement organizations (OPOs) and tissue banks are involved in approaching families for consent. For example, the National Organ Transplant Act requires OPOs to meet certain organizational and staffing requirements; the Act also requires OPOs to assist hospitals in establishing and implementing protocols for making routine inquiries about organ donation by potential donors. No similar requirements exist for tissue banks.[1]

Concerns about Tissue Banking

Several press reports in the Spring of 2000, appearing in the *Orange County Register* and the *Chicago Tribune*, raised a number of concerns about tissue banking. A particular focus of these articles related to financial aspects of the tissue banking industry. Several members of Congress asked the Secretary of Health and Human Services to examine the

tissue banking industry, including the extent to which families were informed about financial arrangements or uses to which tissue might be put.

This Inquiry

The Secretary asked the Office of Inspector General to review two aspects of tissue banking: consent for donation and the overall regulatory structure governing the industry. This report responds to the first of those requests, focusing on informed consent. Our companion report, *Tissue Banking Oversight* (OEI-01-00-00441), provides a profile of the oversight system for tissue banking and addresses limitations in that system.

We use the term "tissue" to refer to skin, heart valves, and musculoskeletal tissue such as bone, cartilage, ligaments, and tendons. Our report does not address eyes and reproductive tissue.

METHODOLOGY

We conducted interviews with senior staff from 30 organizations involved in obtaining, processing, and distributing human tissue; 25 of these organizations were involved in obtaining consent and recovering human tissue.[2] Our interviews focused on their policies, practices, and experiences relative to consent.

With assistance from the National Kidney Foundation, we posted a series of questions on the web site of the National Donor Family Council. These questions sought to provide us with a donor family perspective of experiences with the donation process. We received 50 responses from donor families through this web site. We recognize that the findings from this posting do not constitute a random sample from which projections can be made. Nevertheless, we believe that the responses provide important information and a valuable perspective on the process of obtaining consent.

We interviewed officials and staff, and reviewed documents, from associations involved with tissue banking, including the American Association of Tissue Banks (AATB), National Donor Family Council, Eye Bank Association of America, Association of Organ Procurement Organizations, and North American Transplant Coordinators Organization.

We reviewed State and Federal laws and regulations related to tissue banking, and standards from the AATB.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

The expectations and altruistic motives of donor families are the foundation of tissue donation. Donor families and tissue bank staff told us that in agreeing to donation, families carry some basic assumptions:

Expectation that the donation will enhance the lives of others.

Families expect that their loved one's tissue will be used in meeting important medical needs. The primary expectation is that the tissue will be used for transplantation, as a way of improving the lives of people with medical needs. Many families also provide consent to use tissue for medical research and medical education.

Families may view donation as a way of creating something positive from the death of their loved one. The mother of one tissue donor captured this view when she told us, "If my son helped just one person live a better life, then his donation was worth it." This expectation is reflected in the comments we received from a number of donor families. These families hoped for some type of follow-up with people who had benefitted from their loved one's gift of tissues, as a way of confirming the usefulness of and appreciation for the gift.

Respect for the donor and the family.

Respect has two broad components. First, families anticipate that the donor will be respected. This respect should last through the entire donation process. It includes, for example, respect for the donor's body during tissue recovery. Tissue recovery requires invasive surgery. For families, respect entails that no more harm is done to the body than absolutely necessary.

During processing, distribution, and transplantation, respect entails that the gift be recognized as coming from a donation of human tissue. Musculoskeletal tissue often is processed into many forms. These forms include bone screws, dowels, and bone chips, which have many different medical uses. These final products often bear little resemblance to human tissue; in fact, they look more like tools, hardware, supplies, and devices than what most people would call human tissue. The mother of a donor exemplified the concern that respect be maintained for the donor when she told us, "That 'screw' is not a screw to me — it came from somebody's loved one or child."

Second, donor families expect that their own needs will be respected by the tissue banks. Respect for the family includes discussing the option of donation in a sensitive manner, answering all questions, and ensuring that the timing of and plans for funeral arrangements are not disrupted by tissue recovery.

The AATB's Statement of Principles reflects the importance that the association and its members accord to the importance of respect. Member banks pledge "to honor and treat with respect the gifts that have been donated and to reflect this in all activities related to cell and tissue procurement."[3]

Trust in the organizations involved in procuring and using the donation.

At the time of their loss, families are asked to place enormous trust in tissue banks. Prior to requesting donation, it is unlikely that any relationship existed between the donor family and the tissue bank. Quite possibly, the family may never have heard of tissue donation. Tissue banks request a donation of their loved one's body at the time the family is grieving. As a member of one donor family noted, "It is an extremely emotional display of trust, to allow someone to take parts of a loved one."

Tissue banks we spoke with echoed the sentiments of donor families. One tissue bank director viewed tissue procurement as a public service and said that the bank has the responsibility for ensuring that tissue is "used for the right purposes." Another tissue bank director shared her view of this responsibility: "We are stewards of the gift the family is giving, and it is up to us to handle it in an appropriate manner."

However, the reality of tissue banking raises some underlying tension with families' assumptions.

Commercialization of tissue banking

Families view tissue donation as an altruistic act. This perspective is buttressed by the National Organ Transplant Act, which states that it is "unlawful to acquire, receive or otherwise transfer any human organ [including several defined types of tissue] for valuable consideration for use in human transplantation."[4] Although the act permits recovery of reasonable costs associated with activities such as retrieval and processing, concerns have been raised about whether individuals and firms may be receiving unreasonable financial enrichment from procuring, processing, or distributing the altruistic donation.[5]

No one denies that there are costs associated with processing tissue, conducting research, developing new products and uses, and advancing science. However, the large-scale financial aspects of tissue banking create tensions with an altruistic act.

These tensions have particular relevance to the operation of for-profit firms in what is, at least nominally, an altruistic enterprise based on donation. Publicly-traded companies have raised capital and brought entrepreneurial energy to tissue processing, leading to the development of new processes and products. Yet, it is precisely at this point that tension arises. The concern may be best characterized as unease about a focus on the "bottom line," as portrayed in the following question: If a company's primary interest is financial benefit to its stockholders, is it making choices to put tissue to more lucrative uses over

medical needs?[6]

A second facet of tension with commercialization relates to the level of salaries and costs incurred by both non-profit and for-profit firms. Although reasonable costs are permitted, there is no definition of, and undoubtedly no consensus about, what constitutes "unreasonable costs." In fact, no guidelines are in place regarding disclosure of costs, and no comparative data are available publicly on the range of costs that would permit such a determination.

Finally, the industry is intensely competitive, with firms establishing proprietary patents on a number of products and processes. Some observers view this as primarily an effort to gain competitive advantage and market share in the distribution of tissues.

In a vacuum, these issues do not raise concerns. Yet in an industry that is premised on donation of parts of a loved one's body, it should not be surprising that donor families could feel misled as they question why "everyone is making money off of this altruistic gift except the donor and the donor's family."

The importance of concerns about commercialization for informed consent relates to whether families may wish to know about commercial relationships that exist between the agency to which it makes an altruistic donation, and an entity — be it non-profit or for-profit — that realizes revenue from the gift. If they are not made aware of these relationships, it may be difficult to say that their consent truly is informed.

Tissue viewed as a commodity

Maintaining respect for the donor and the donor's family is an underpinning of the tissue system. As we discuss above, tissue is processed extensively for many different uses. The marketing of human tissue as a commodity bears particular relevance to donor families' assumption that their loved one's tissue will be treated with respect and honor, and that it will be respected by the users and the recipients of tissue.

The packages in which human tissue is supplied — bottles, vials, containers shrink-wrapped in plastic — resemble many other medical supplies. The labeling does state that the contents are human tissue, but this is related to concerns about safety and disease transmission rather than respect for the donor. The packaging does not indicate that the enclosed materials derive from *donated* human tissue.

We reviewed marketing materials from both for-profit and non-profit companies. These product brochures look like typical medical supply catalogues, contributing to a perception that tissue is no different from other supplies. As with the packaging, the marketing materials rarely indicate that the materials derive from *donated* human tissue.

Cosmetic uses of tissue

A number of products used in reconstructive surgery utilize donated tissue, particularly

skin. These products are used in procedures that most people would, no doubt, consider medically appropriate and necessary. Examples of such procedures include alleviating serious scarring or constructing a bladder sling for treatment of urinary incontinence.

On the other hand, there clearly are some uses of these products that many people would consider to be non-essential cosmetic uses.[7] It is not clear how much tissue goes for such cosmetic uses; because the actual use of these products is determined by physicians and patients, tissue banks that manufacture them do not have that information. However, a family may be reluctant to give its consent for donation if it is aware that the gift would be used for purposes that are not medically indicated.

The American Medical Association's policy provides a useful framework for considering the differences between cosmetic and reconstructive surgery. That policy states that "*cosmetic* surgery is performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem. *Reconstructive* surgery is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance."[8]

Fundamental factors limit the amount of information that is given to families.

Families are asked to give their consent at a point in time when they are extremely vulnerable.

The recent, often sudden and unexpected, death of a loved one means that families are likely to be distraught when they are asked for consent to donate. In the face of sudden tragedy, they may simply be unable to understand detailed information about tissue donation.

Tissue donation is a complex topic. Tissue banks must obtain consent for donation within hours following the death of a loved one. Because the family may be in shock, discussing multiple aspects of tissue donation and tissue banking — recovery, processing, distribution, commercial relationships — may go well beyond the capacity of families to comprehend what they are hearing. The father of a tissue donor echoed this sentiment when he commented to us, "I doubt donor families can process much information; they hear very little at a time when they are immersed in profound shock and grief."

At the same time, families may not wish to receive detailed information about tissue banking.

Often, families know they want to consent to donation, but do not want to hear specific details about the process. As one tissue donor mother told us, "I really didn't need any more information than what was provided; frankly, I wouldn't have been able to deal with much more at that point." Her thoughts were echoed by a tissue bank director who told

us that it is crucial to be able to give families as much or as little information as they want, depending on where they are in the grief process.

Tissue bank staff with whom we spoke cited the balance they must strike when speaking with families. Much information needs to be communicated to the family at the time of consent; at a minimum, authorization for removal of specific tissues is required. Families also must agree to whether the tissue may be used only for transplantation, or for other uses such as research and education.

Tissue bank staff told us that families generally have two primary concerns: whether the family will incur any costs for donating tissue and whether the body will be suitable for an open-casket viewing. They noted that it is rare for families to ask about other concerns. On the other hand, some families may wish to have more information to help them reach a decision, or they may wish to receive more information that they could reflect upon at a later date. The challenge for those seeking consent is to gauge how much detail a particular family wishes to receive.

Obtaining consent and documenting a donor's medical suitability require time-consuming and invasive questioning about a recently deceased loved one.

Because tissue can transmit disease, FDA requires tissue banks to screen donors for evidence of behaviors that place them at high risk for HIV and hepatitis.[9] This screening requires completion of a lengthy medical and social history questionnaire as part of determining donor suitability. Tissue bank personnel who administer the medical and social history questionnaire to families note that the process may take as long as an hour or more to complete. The tissue bank staff must administer this questionnaire shortly after the family consents to donation.

Donor families must answer questions about the deceased's medical history and personal behaviors, including uncomfortable questions about drug and alcohol use, and about sexual behavior. Under any circumstances, questions such as these are intrusive. After the death of a loved one, this effect undoubtedly is amplified.

Current practices in requesting consent raise concerns about how and what information is provided to families.

Many tissue banks rely on staff from other organizations to obtain consent.

We interviewed staff from 25 banks that recover tissue; 14 of these banks rely primarily on their own staff to request consent from families, and 11 banks rely on others to make the requests. The American Association of Tissue Banks conducted an informal survey of its members. AATB found that 42 percent of accredited tissue banks use their own staff to request consent for tissue donation, while the other 58 percent of banks use individuals not employed by the bank for requesting.

About half of the external requestors are staff from organ procurement organizations

(OPOs). OPOs play an important role in tissue donation, even if they do not operate a tissue bank. Recent changes to the Medicare conditions of participation for hospitals gave OPOs an important gatekeeping function by requiring a hospital to notify its OPO of all deaths. Thus, even for persons who do not meet the stringent criteria for organ donation, OPOs play a role in referring the call to the appropriate tissue bank and, in some cases, seek consent from the family for tissue donation.[10]

External requestors include staff from telephone triage agencies with which the tissue bank contracts for the specific purposes of requesting consent. Tissue banks also rely on hospital staff, primarily nurses, chaplains, and social workers, to obtain consent from families. Tissue banks may wish to keep hospital staff involved in and committed to donation. These staff may well have been in close contact with the family, and families may be more trusting and receptive to donation when it is discussed by these caregivers.

Other tissue banks prefer to handle the consent process themselves. The director of one OPO that also operates a tissue bank told us she "simply feels more comfortable knowing that trained coordinators are doing the requesting." This approach also benefits hospitals; it is a way of relieving a hospital of liability for its own staff should problems arise.

Tissue banks often request consent over the telephone, rather than in person.

Consent requests for tissues contrast sharply with requests for organ donation. In requesting organ donation, OPO staff seek consent from the family while they are still at the hospital. OPO staff often have spent long hours with the family prior to disconnecting the ventilator, and they likely have established a rapport with that family.

In our interviews, 16 of 25 tissue banks that recover tissue said that they primarily request consent over the telephone, rather than in person. In most cases, tissue banks make these requests after the family has left the hospital. Tissue bank staff told us that it is more productive to give the family time to return to the familiar surroundings of home, rather than the coldness of a hospital. At a practical level, it also would be quite difficult for the tissue bank staff to travel to every hospital when someone has died in order to request donation.

There may be little training and accountability of external requestors.

Tissue banks train and monitor their own staff who request consent. Training programs typically include classroom lectures, written materials, presentations, observing other requestors, role playing, and mentoring by seasoned requestors. Many banks send requestors to training courses offered by organizations with longstanding expertise in the field. Most tissue banks we spoke with also provide their staff with continuing education.

Training programs for tissue requestors not employed by the bank tend to be briefer. Training programs for external requestors at tissue banks we spoke with ran about 4 hours on average. Training generally comprises presentations by tissue bank staff and covers topics including how to interact with families, the use of tissues, and how tissues are recovered. A few tissue banks offer longer programs that include role-playing exercises.

After the initial training, only a small number of tissue banks we spoke with offer continuing education or follow-up training to external tissue requestors.

Training for tissue donation also may take place through an OPO's designated requestor training program. Yet, as we have shown elsewhere, few OPOs conduct this training.[11] Tissue bank staff we interviewed also indicated that OPOs give only limited attention to training about requesting tissue donation, because organ donation is often seen as a higher priority than tissue donation. This difference in emphasis is likely to be more pronounced in areas where there is competition between the tissue bank and the OPO.

Providing in-depth training of external requestors faces some major constraints. Tissue bank directors we interviewed noted that it is difficult for hospital staff to take time from their duties for intensive training as a tissue requestor. Additionally, tissue banks that rely on hospital staff to request consent may be unable to select the hospital staff to be trained. Thus, staff who may not want to be tissue requestors may be trained for the process and, subsequently, may do a poor job of it.

Even among those tissue banks that train external requestors, we found that few actively assess their performance. The primary vehicle we found for assuring accountability was that some tissue banks use their own staff to contact the donor family at home to complete the medical-social history questionnaire. These banks told us that having their own staff speak with the donor family provides a checkpoint for the consent process, because staff can answer questions, provide more information, and reaffirm the consent.

Tissue banks provide donor families with little written material at the time of donation.

Few tissue banks routinely give families a copy of the signed consent form. The consent form, however, is the legal authorization governing the removal of tissue and specifying purposes for which the tissue may be used. One tissue bank told us that it asks family members if they want to receive more information. Other tissue banks indicated that they would give the family the form if someone requested it. However, requiring a family to make such a request places it in a deferential position, when the bank could proactively make the consent form available.

Following donation, it is general practice for tissue banks to send families a letter thanking them for the gift and expressing condolences. We reviewed copies of these letters from 11 tissue banks; about half gave a general description of which tissues were recovered, and the other half conveyed information in broad, generic terms about how tissue can be used to improve people's lives. Many of the tissue banks we spoke with provide additional materials about grieving and about support groups.

Aside from this letter, tissue banks provide little additional written information to families about tissue use, processing, or other entities with which they have financial arrangements. Tissue bank staff we spoke with told us they are hesitant to provide more information to families, either at the time of consent or afterwards, because the family is

grieving and may not want to think about the donation.

Many donor families told us that consenting to donation was a positive outcome that came from their loved one's death. Because families may not comprehend everything that is told to them at the time of donation, more information may be beneficial at a later date. One donor mother captured this sentiment when she told us, "I know there are many families who would like to have some reading material to refer to when or if they are ready, since there is so much information that is not heard within this horrific moment."

Until recently, standards governing how families are approached and what they are told about tissue donation have been nonexistent. However, some advice and guidance have emerged.

Federal laws and regulations do not address the manner in which tissue banks obtain consent.

The Health Care Financing Administration has no statutory or regulatory authority over tissue banks. However, the 1998 Medicare conditions of participation for hospitals relating to organ, tissue, and eye donation require hospitals and tissue banks to work together to establish donor suitability criteria. The regulations also require hospitals to ensure that all families of potential donors are informed of their options to donate organs, tissues, and eyes, and that programs for training hospital-based requestors are designed in conjunction with the local tissue banking community.[12] However, the regulation does not provide specific guidelines on the content, circumstances, or manner of approaching donor families.

The Health Resources and Services Administration (HRSA) provides resources and support to the transplantation community. HRSA recently published a resource guide that provides information and approaches on training hospital staff and procurement agencies in working and communicating with grieving families as part of the donation process.[13]

The Food and Drug Administration's (FDA) authority over tissue banks derives from Public Health Service Act provisions authorizing regulations to prevent the spread of communicable diseases. The agency requires that donor screening and testing for HIV-1 and -2 and for Hepatitis B and C. FDA regulations do not address the issue of obtaining consent for donation; however, the regulations do require tissue banks to interview someone such as a close relative about the donor's medical history and social behavior.[14]

States' Uniform Anatomical Gift Acts do not address what information tissue banks should provide in obtaining consent.

All States and the District of Columbia have enacted versions of the Uniform Anatomical Gift Act.[15] These laws establish procedures for competent adults to make anatomical gifts by completing and signing a legal document. These gifts are irrevocable at the donor's death. The laws also include some stipulations on obtaining consent, such as the

order in which next-of-kin may make decisions, documentation required, or the number of persons who must provide legal witness. However, these laws do not address the content of informed consent.

The gift acts in some States specify the informed consent document that must be signed. The consent form itself, however, is a legal document, not a mechanism for sharing pertinent information about donation with the family.

The National Donor Family Council has proposed key elements of an informed consent policy for tissue donation.

The National Donor Family Council (NDFC) represents about 8,000 donor families. The NDFC recently approved a position statement on tissue donation that addresses important considerations for discussing donation with donor families. The full position statement appears in Appendix A. Key elements include:

- Explanations on how tissue is recovered, processed, stored and distributed;
- Explanations that the tissue may be used or modified for transplantation;
- Explanation that the family may limit or restrict the use of tissue; and
- Requirements that the consent form be reviewed with families and that a copy be offered to the family.

Organizations representing the tissue banking industry have issued a statement that addresses elements of informed consent to be included in discussions with families.

The American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations, and the Eye Bank Association of America, issued a joint statement in December, 2000. The full position statement appears in Appendix B. AATB, which accredits 58 cadaveric tissue banks, is incorporating the elements contained in this statement into its accreditation standards. The updated standards are scheduled for publication in January, 2001.

The statement addresses basic elements of informed consent which should be provided to all families. These basic elements include:

- Identification of specific tissues that are being requested for donation;
- Explanation that retrieved tissues may be used for transplantation, therapy, research, or education; and
- A general description of the recovery process.

The statement also recognizes that families may seek additional information about donation. If so, additional explanations should be provided to address such issues as:

- The possibility that the gift may take a different form than originally recovered;
- Transplantation may include reconstructive and aesthetic surgery; and
- Multiple organizations (non profit and/or for profit) may be involved in facilitating the gift.

CONCLUSION

Tissue banking and processing practices have gradually diverged from donor families' expectations in recent years. For donor families, the altruistic donation of tissue from a loved one is a charitable act. Donation is made with few expectations other than that it will be used to enhance the lives of others, that the donor will be treated with respect, and that the organizations with whom tissue banks work will take special care to ensure that the gift is used for these purposes.

Today's tissue banking industry and the beneficial uses of human tissues and related products have become more complex and costly. New ways of using tissue for medical treatment have been developed. Tissue banking has been infused with capital and entrepreneurial practices. Processed tissue often is marketed and sold like any other medical product. For some, these practices call into question the non-profit basis of the tissue banking community.

Despite these changes, the foundation of the industry remains that of human tissue freely donated by individuals and their families at a most difficult and extraordinarily sensitive time.

The special nature of human tissue, and the circumstances under which it is made available, call for certain steps to be taken above and beyond those that would apply to most other business or philanthropic enterprises. In the following section, we share our recommendations that take these into account.

RECOMMENDATIONS

Importance of Increasing Donation

The Office of Inspector General has examined issues related to organ, tissue, and bone marrow donation, allocation, and transplantation for more than a decade. The principles underlying our work have consistently focused on enhancing equity for patients, improving access to transplantation, and encouraging donation.

Encouraging donation was of paramount importance to us as we developed these recommendations. It is our hope that these recommendations will encourage donation. Our recommendations encourage joint action among groups representing the tissue banking industry, donor families, and the government.

The Department of Health and Human Services

The Health Resources and Services Administration should work with groups representing donor families and the tissue banking industry to develop guidelines for conveying information to families about tissue donation.

HRSA's Division of Transplantation supports the development of programs to increase donation. In that role, HRSA has gained considerable expertise about effective practices in requesting consent. The agency could act as a resource to convey information about donation to tissue banks and families.

HRSA's efforts could focus on such areas as:

- Identifying principles and guidelines that should underpin consent requests, such as those outlined recently by the National Donor Family Council and jointly by the American Association of Tissue Banks, Association of Organ Procurement Organizations, and the Eye Bank Association of America;
- Making suggestions as to the type, format, and content of written information about donation that tissue banks could share with families;
- Making recommendations on information that would be useful for training tissue bank staff and external requestors; and
- Making recommendations on assessment tools that would be useful in evaluating the effectiveness of requestors.

The Health Care Financing Administration should address informed consent for tissue donation through the conditions of participation for hospitals and for organ procurement organizations.

As we note above, HCFA requires hospitals to assure that the family of each potential donor is aware of its options to donate. This requirement applies to tissue donation, as

well as to donation of organs and eyes.

Elsewhere in this report, we recommend that HRSA work with donor family groups and the tissue banking industry to develop guidelines for conveying information to families about tissue donation. HCFA could use these guidelines as it provides information about the hospital conditions of participation for organ, tissue, and eye donation. The agency could publicize these principles through the "Questions and Answers" document posted on the HCFA Internet site. For example, the agency may wish to encourage hospitals to include a protocol for informed consent in their agreements with tissue banks, using the recommended guidelines in those protocols.

In the longer term, the agency may wish to examine the Medicare conditions of coverage governing organ procurement organizations. In that examination, the agency could consider whether it would be beneficial to include additional requirements to strengthen working relationships between OPOs and tissue banks. Such requirements might include:

- Holding OPOs responsible for informed consent for tissue donor families when requesting consent on behalf of tissue banks; and
- Requiring OPOs to include tissue banks in the training that they conduct for designated requestors.

The Tissue Banking Industry

At the time of obtaining consent, tissue banks should provide families with written materials that provide fuller disclosure about the uses of tissue and the nature of the gift.

Tissue banks could do a better job of providing basic information to families, either at the time they ask them to consent to donation, or in the days immediately following that decision. At a minimum, this material should include:

- A copy of the signed consent form. We believe that this is a basic legal protection for the family, as well as a recognition of the nature of the gift to which they have consented;
- Written information to the family on how it can follow up with the tissue bank in the case concerns arise;
- A full description of the uses to which donated tissue may be put; and
- A list and description of other entities with which the bank has relationships for processing and distributing tissue.

Written materials should be appropriately thorough. Such materials would serve as a way to supplement the information that requestors provide to the family during their conversation about donation, while providing requestors with the flexibility to adapt that discussion to the unique needs and responses of each donor family.

Tissue processors and distributors should ensure that information accompanying their product clearly indicates it is derived from *donated* human tissue.

The FDA does not currently have labeling requirements for packaged tissue, and the AATB's standards (which apply only to banks accredited by the association) address labeling within the context of ensuring that users know it is a biologically-based product, capable of transmitting disease. Neither set of standards addresses donor families' concerns that recognition be given to the fact that the products are the result of a freely made donation of human tissues.

The following steps could help to address perceived concerns that donated human tissue is no different from any other medical product. Tissue banks should:

- Indicate clearly on all tissue packaging that the contents derive from donated human tissue; and
- Indicate clearly on all marketing and informational brochures that these products derive from donated human tissue.

This recommendation responds to concerns that tissue is viewed as a commodity, rather than an altruistic donation. Implementing it would require only minor changes in packaging and marketing materials. But it would go a long way towards showing ongoing respect for the donor and the gift of donation.

Tissue banks should foster greater accountability for the performance of those who request consent for donation.

We found wide variation in practices among tissue banks with respect to how consent for donation is requested, who requests consent, and how these individuals are trained and monitored. There is no doubt that the responsibility for ensuring that requestors are providing accurate, sensitive, and appropriate information rests directly with the tissue bank. To ensure greater accountability of requestors, tissue banks should:

- Ensure that their requestors are fully and appropriately trained. This applies both to requestors from their own organizations as well as other entities, such as hospitals;
- Provide continuing education for requestors; and
- Conduct ongoing assessments of requestor performance to ensure that they are providing full and accurate information to families approached for donation.

The tissue banking industry should work with representatives of groups representing donor families to explore a process for periodic public disclosure about tissue banks' financing.

Non-profit entities are already required to disclose information about the sources and uses of funds received; publicly-owned businesses submit annual public reports to the Securities and Exchange Commission. These disclosures contribute to public accountability

and can serve as a basis for building greater trust among donors, families, and tissue banks.

The purpose of the examination we recommend here is to respond to family and general public concerns about knowing the type and extent of financial arrangements which the tissue bank has with other entities, both nonprofit and for profit. The examination would consider whether financial information would be useful as part of a package of information provided to donor families. The examination would consider:

- What types and how much financial information would be useful for families and individuals in making decisions about donation;
- The advantages and disadvantages of financial disclosure, including its potential impact on donation; and
- The content, style, and format of disclosure.

COMMENTS ON THE REPORT

We received comments on a draft of this report from the Department of Health and Human Services. They are supportive of our findings and recommendations. The full text is included in Appendix C.

Our work in tissue banking continues. We will maintain an active watch on how the tissue banking community responds to the concerns that we have raised.

APPENDIX A

National Kidney Foundation®
Making Lives Better

NATIONAL DONOR FAMILY COUNCIL
EXECUTIVE COMMITTEE

POSITION STATEMENT ON TISSUE DONATION

The National Donor Family Council (NDFC) of the National Kidney Foundation recognizes and supports tissue donation as an end-of-life option for donor families and recognizes its life-enhancing capacity to help thousands who are awaiting tissue transplantation.

The NDFC strives to enhance the sensitivity and effectiveness of the organ and tissue procurement process. To further this mission, the NDFC believes that tissue donation should always be treated as a gift of life. We believe that the tissue community as a whole must promote sensitivity to and support for organ and tissue donor families.

While the NDFC recognizes that financial resources are an important factor in maintaining the highest quality of tissue services, it is our position that tissues must be collected, processed, stored and distributed in an efficient manner that minimizes costs and maximizes the benefit to patients. The NDFC believes that donated tissue must be used in a way that promotes healing for people with the greatest need.

The tissue community should resist the tendency to make the generous gift of donated tissue a commodity. Professionals should refrain from referring to donated tissue as a "product." All packaging for donated tissue should include a statement indicating that the package contains donated tissue and is a gift of life. The tissue community should educate health care professionals, including physicians who use donated tissue, about the donor family perspective and the nature of the gift. The tissue community should also work to raise awareness among funeral services professionals and strengthen their commitment to follow the wishes of donor families. The tissue community must pay all expenses incurred by the donor family that are directly associated with tissue donation, including any increased funeral charges.

As approved by the NKF National Donor Family Council Executive Committee and the NKF Board of Directors, September 25, 2000

NOTE: This Policy Statement is subject to further revision based on a survey of donor families currently in progress

APPENDIX A

National Kidney Foundation®
Making Lives Better

NATIONAL DONOR FAMILY COUNCIL
EXECUTIVE COMMITTEE

INFORMED CONSENT POLICY FOR TISSUE DONATION

As with organ donation, the National Donor Family Council (NDFC) of the National Kidney Foundation believes that a crucial element of the tissue donation process is the informed consent of the donor family. With respect to tissue donation, the informed consent of the donor family must, at an absolute minimum, include a voluntary decision based on full disclosure of the facts.

Full disclosure includes the following elements:

1. Donor families should be given a general explanation of the tissue process, including:
- medical and social history
- communicable disease testing
- laboratory testing
- medical suitability
- how tissue is recovered, processed, stored and distributed

2. Donor families must be told what tissue can be recovered from their loved ones based on medical suitability. If heart valves will be recovered, families must be informed that the heart will be removed from the donor's chest and sent to a facility where the valves will be removed. If the entire eye will be removed for corneal donation, families should be informed.

3. Donor families must be informed that tissue can be used or modified in various ways for transplantation in a life-saving capacity, transplantation in a life-enhancing capacity, and medical research or education.

4. Donor families must be told that they have the right to limit or restrict the use of the tissue.

5. Donor families must be told about the likelihood that the donated tissue will be stored, how it will be stored, the duration of storage, and the possibility that the tissue may not be utilized.

6. The completed consent form must be reviewed with the donor family before final consent, and a copy should be offered to the family. Other written material explaining tissue donation should be offered to the family.

7. Donor families must be given the option of receiving acknowledgment of their gifts. This acknowledgment should include both disposition and any recipient information available at that time, while protecting the anonymity of both donor and recipients. To obtain additional information about the gift, the donor family should be provided with contact information (including phone number and address) for the recovery agency.

As approved by the NKF National Donor Family Council Executive Committee and the NKF Board of Directors, September 25, 2000
NOTE: This Policy Statement is subject to further revision based on a survey of donor families currently in progress

APPENDIX B

Model Elements of Informed Consent for Organ and Tissue Donation

American Association of Tissue Banks
Association of Organ Procurement Organizations
Eye Bank Association of America

Human organ and tissue transplantation has become an important and growing part of modern medical practice. Advances in medical science have made it possible for millions of Americans to receive these life-saving and life-enhancing gifts. None of this would be possible, however, were it not for the tens of thousands of donors and donor families who give their organs and tissues to help their fellow men and women.

The decision to donate must, therefore, be an informed consent, and it must be conducted under circumstances that are sensitive to the consenting person's situation. Information concerning the donation should be presented in language and in terms that are easily understood by the consenting person. The consent should be obtained under circumstances that provide an opportunity to ask questions and receive informative responses. An offer should be made regarding the availability of a copy of the signed consent form, and information should be provided regarding ways to reach the recovery organization following donation. Consent should be obtained in accordance with federal, state and/or local laws and/or regulations. The person seeking the consent should be trained to appropriately answer any questions that the consenting person may have. In addition, coercion should not be exerted in any manner, nor monetary inducement offered to obtain consent for donation. The identification of who may be the appropriate person to consent to donation, and whether the consent of any person in addition to the donor needs be obtained, should be evaluated in accordance with the applicable laws and organizational policy and is not addressed in this statement.

The following list of "Basic Elements of Informed Consent" is intended to highlight the information that may be considered critical to informed decision making by a family member or other legally authorized person, who is being approached for consent to organ and/or tissue donation. This listing, whether communicated verbally or included on consent forms, is not intended to preempt any applicable federal, state, or local laws or regulations that may require more or less information to be disclosed for informed consent to be legally effective.

Basic Elements of Informed Consent

In seeking informed consent, the following information should be provided to the person(s) being approached for consent:

- A confirmation/validation of the donor's identity and his or her clinical terminal condition.

- A general description of the purposes (benefits) of donation.

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- Identification of specific organs and/or tissues (including cells) that are being requested for donation (with subsequent information provided on specific gifts recovered).
- An explanation that the retrieved organs/tissues may be used for transplantation, therapy, medical research, or educational purposes.
- A general description of the recovery process (including timing, relocation of donor if applicable, contact information, etc.).
- An explanation that laboratory tests and a medical/social history will be completed to determine the medical suitability of the donor, including an explanation that blood samples from the donor will be tested for certain transmissible diseases.
- An explanation that the spleen, lymph nodes, and blood may be removed, and cultures may be performed, for the purpose of determining donor suitability and/or used to determine compatibility of donor and recipient.
- A statement granting access to the donor's medical records, and that the medical records may be released to other appropriate parties.
- An explanation that costs directly related to the evaluation, recovery, preservation, and placement of the organs and tissues will not be charged to the family.
- An explanation regarding the impact the donation process may have on burial arrangements and on appearance of the body.
- Any additional information required by federal, state and/or local laws and/or regulations.

Additional Elements of Informed Consent

In some situations, there may be additional information that should be known by the consenting person(s), or that might be helpful for family decision making. At a minimum, if the donor family inquires about any of these or additional matters, explanations should be provided.

The guiding principle for the use of these "Additional Elements of Informed Consent" is to advance simplicity and reasonableness in seeking informed consent, i.e. include these elements or additional comments if they are appropriate and might clarify any

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exigencies. For example, if there is the likelihood that the patient will become a Medical Examiner's case, then it should be appropriate to so inform the family. If it is unlikely that donated tissue is going to be used for aesthetic surgery, then it would not be reasonable to address this issue in the family approach.

One or more of the following elements of information may also be appropriate for communication to the person(s) being approached for consent, depending upon the circumstances surrounding the donation and the potential gift(s):

- A description of any involvement by the Medical Examiner and/or Coroner, including an explanation that an autopsy may be performed.
- An explanation that transplantation may include reconstructive and aesthetic surgery.
- A reference to the possibility that the final gift may take a different form than originally recovered.
- An explanation that multiple organizations (nonprofit and /or for profit) may be involved in facilitating the gift(s).
- Reference to the possibility that tissue and/or organs may be transplanted abroad.

American Association of Tissue Banks

Association of Organ Procurement Organizations

Eye Bank Association of America

November 30, 2000

Comments from the Department of Health and Human Services

APPENDIX C

THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DEC 2 6 2000

TO: Inspector General, HHS

SUBJECT: Department Comments on OIG Report on Informed Consent in Tissue Donation

I commend the Office of the Inspector General (OIG) for its quick response to my request to review the status of informed consent for tissue donors.

The Department finds considerable merit in the OIG's recommendations toward making more -- and more meaningful -- information available to tissue donors and tissue donor families. Working with the industry and donor families to facilitate better understanding of this process is likely to produce positive results.

The Department notes that important activities relevant to the OIG's recommendations are underway:

> The Health Resources and Services Administration (HRSA) already works closely with donor and recipient families and other representative groups to develop educational information about organ and tissue donation. To include tissue banks in such activities would be a logical extension.
>
> The Health Care Financing Administration (HCFA) currently is engaged in several activities with hospitals, organ procurement organizations, and tissue banks to increase organ and tissue donation. The OIG recommendations for additional efforts toward ensuring that donors and donor families receive information adequate for informed consent is consonant with the current activities and should be readily accommodated. While tissue banks are not directly under HCFA's jurisdiction, they have worked closely with HCFA and organ procurement organizations with a view to having appropriate donors referred to them.

If the OIG's recommendations that are directed toward the tissue industry were to be implemented in full and promptly, such action could go far toward easing the concerns that have been raised about the uses to which donated tissues are put. Tissue donors and tissue donor families undoubtedly would welcome increased efforts toward ensuring informed consent, giving explicit recognition for the donation on the packaging associated with tissues or products prepared from them, and providing more insight about the fiscal aspects of tissue handling and processing. Although the Department has no way to compel action in these areas by the tissue industry, the pertinent agencies of the Department are prepared to support the industry in taking such steps.

Kevin Thurm

APPENDIX D

Endnotes

1. The National Organ Transplant Act specifies that organ procurement organizations must be nonprofit entities, establishes requirements for their service area, and imposes certain organizational and staffing requirements. (42 U.S.C., Section 273(b))

2. Of the tissue bank officials we interviewed, five banks only process and distribute tissue; they do not recover tissue and would not be directly involved in obtaining consent. In addition, eight banks that recover tissue also do some processing and distribution.

3. "AATB Statement of Ethical Principles," adopted November 1994.

4. 42 U.S.C., Section 274e. This is the one provision of the National Organ Transplant Act that specifically addresses human tissue. The act defines organ to include "bone marrow, cornea, eye, bone, and skin or any subpart thereof," as well as vascular organs such as kidney, liver, heart, lung, and pancreas.

5. The Act specifies that the term "'valuable consideration' does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ."

6. The web sites of the major processing firm contain information and press releases on new products and uses. Web sites of all the for-profit firms that we examined have a prominently displayed category addressing investor relations, as well.

7. Often cited examples include enhancements of lips or other body parts among Hollywood starlets. During our visit to one tissue processing firm, we were struck by framed blowups of covers from various fashion magazines that were displayed prominently on the walls of the reception area.

8. American Medical Association Policy H-475.992

9. 21 C.F.R. 1270.21, added at 62 *Fed.Reg.* 40,445, July 29, 1997.

10. Organ donation generally requires that the donor be declared brain dead (*i.e.,* death through cessation of neurologic function), rather than suffering cardiac death. A small number of total deaths — perhaps 12,000 - 15,000 at the most — meet this criteria in any given year.

11. U.S. Department of Health and Human Services, Office of Inspector General, "Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule," (OEI-01-99-00020), August 2000.

12. 42 C.F.R., section 283.45, added at 63 *Fed.Reg* 33,875, June 22, 1998.

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13. U.S. Department of Health and Human Services, "Roles and Training in the Donation Process: A Resource Guide," September 2000, available at http://www.organdonor.gov.

14. 21 C.F.R., Parts 16 and 1270, added at 62 *Fed. Reg.* 40,429, July 29, 1997. The FDA issued these regulations under the legal authority of section 361 of the Public Health Service Act. This section authorizes the Secretary to make and enforce regulations judged necessary to prevent the introduction, transmission, or spread of communicable diseases.

15. The original Uniform Anatomical Gift Act was first developed in 1968 by the National Conference of Commissioners on Uniform State Laws. Many States have incorporated the features of a revised version developed in 1987.

BRIEF REPORTS

Generation of a Transplantable Erythropoietin-Producer Derived From Human Mesenchymal Stem Cells

Takashi Yokoo,[1,2,6] Akira Fukui,[1,3] Kei Matsumoto,[1,2] Toya Ohashi,[2] Yoshikazu Sado,[4] Hideaki Suzuki,[2] Tetsuya Kawamura,[1] Masataka Okabe,[3] Tatsuo Hosoya,[1] and Eiji Kobayashi[5]

Differentiation of autologous stem cells into functional transplantable tissue for organ regeneration is a promising regenerative therapeutic approach for cancer, diabetes, and many human diseases. Yet to be established, however, is differentiation into tissue capable of producing erythropoietin (EPO), which has a critical function in anemia. We report a novel EPO-producing organ-like structure (organoid) derived from human mesenchymal stem cells. Using our previously established relay culture system, a human mesenchymal stem cell-derived, human EPO-competent organoid was established in rat omentum. The organoid-derived levels of human EPO increased in response to anemia induced by rapid blood withdrawal. In addition, the presence of an organoid in rats suppressed for native (rat) EPO production enhanced recovery from anemia when compared with control animals lacking the organoid. Together these results confirmed the generation of a stem cell-derived organoid that is capable of producing EPO and sensitive to physiological regulation.

Keywords: Mesenchymal stem cell, Erythropoietin, Anemia, Kidney.

(*Transplantation* 2008;85: 1654–1658)

Erythropoietin (EPO) stimulates red blood-cell production and is produced mainly in the kidneys. Recombinant human EPO is widely administered to treat and mitigate renal anemia in chronic renal failure (CRF) patients (*1*), improving quality of life and reducing mortality and morbidity (*2, 3*). In fact, costly recombinant human EPO treatment (more than $9,000 per person per year) accounts for the highest annual drug sales worldwide (*4*). In light of the predicted rise in CRF in aging populations globally, the need to develop a cost-effective alternative is apparent. Transplanting EPO-producer from a human source seems to be the ideal therapeutic focus for CRF because it would be more cost effective and less likely to result in the serious complication of pure red-cell aplasia, because of the possibility of auto-regulation.

Treatment successes have been reported with gene therapy (*5*), in which the EPO gene is transferred directly to the recipient in vivo, and cell therapy (*6*), which involves putting the EPO gene into isolated cells that are then transplanted into the recipient organism, in combination with an artificial regulatory system (*7–10*). These methods, however, require viral vector-mediated delivery, which carries ethical issues and may not adequately mimic the physiological oxygen-dependent control of EPO production due to its complex and sensitive regulation in vivo (*4*). The ultimate therapeutic approach, then, is to establish functional tissue derived from human autologous stem cells, capable of generating endogenous levels of HuEPO and retaining physiological regulatory pathways to deal with conditions such as anemia. We therefore attempted to establish the transplantable HuEPO producer from human mesenchymal stem cells (hMSCs).

Establishment of Human Mesenchymal Stem Cell-Derived Organoid

Currently, the successful differentiation of stem cells into EPO-producing tissues has thus far proved elusive. To address this issue, we first generated an hMSC-derived organoid that is morphologically and functionally similar to the kidney as previously described (*11*). Briefly, hMSCs purchased from Cambrex Bio Science (Walkersville, MD) were

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transfected with glial cell-derived neurotrophic factor (GDNF) using AxCAhGDNF (*12*) and subsequently injected at the site of kidney organogenesis of growing rat embryo (E11.5) (Supplementary Fig. 1 and Movie, available for viewing online only). GDNF is normally expressed in metanephric mesenchyme at this stage, and the interaction between GDNF and its receptor, c-ret, is required for epithelial-mesencymal signaling (*13*). Whole embryo was then cultured according to the whole embryo culture system described previously (*14*), and kidney rudiments were dissected for metanephric organ culture for 24 h (*15*). We previously confirmed that this relay-culture system is able to differentiate exogenous hMSCs into kidney structure comprising tubular and glomerular epithelial cells as well as interstitial cells (*11*), where EPO is physiologically produced (*16*). Resultant kidney rudiments were transplanted in the omentum of host rats (Sprague-Dawley; Sankyo Laboratory Service, Tokyo, Japan) and during the same surgery, host rats had the right kidney removed to enhance the development of kidney rudiment (*17*). It was previously reported that metanephros transplanted into omentum evokes minimal immunogenicity (*18*). In support of this, we found a negligible number of mononuclear cells infiltrating the established organoid even 4 weeks after transplantation (data not shown). This additional development in the omentum may lead to vascular integration of the host circulation into the transplanted kidney rudiment (*19*) (resultant kidney-like structure was termed organoid). Detailed methods for establishing organoid are provided separately in the on-line Supporting Information.

Production of Human Erythropoietin From Organoid

Real-time polymerase chain reaction of RNA extracted from organoid tissue 2 weeks after implantation indicated the expression of both human and rat EPO mRNA (Fig. 1A); EPO was not expressed in the kidney rudiment before transplantation. This finding suggested that reciprocal interactions between stromal cells in the transplant and integrated endothelial cells are important for the differentiation of EPO-producing cells. In addition, the organoid must acquire the potential for EPO production during development in the recipient omentum. Sequence analysis using a BigDye Terminator v3.1 Cycle Sequencing kit (Applied Biosystems, Faster City, CA) confirmed the expressed EPO gene product to be of human and rat origin, showing that the established organoid could produce both human and rat EPO, probably reflecting the chimeric nature of the organoid (*11*) (Fig. 1B). Immunobistochemical staining with an antibody to HuEPO (Santa Cruz, CA) further confirmed that the organoid contained EPO-producing cells (Fig. 1C). The HuEPO antibodies cross-react with rat EPO, whereas the antibody for β2-microgloblin (hβ2MG; BD Biosciences, San Diego, CA) is human-specific (data not shown). We therefore double stained for hβ2MG and EPO, revealing that some hβ2MG-immunopositive cells also expressed HuEPO (Fig. 1D). These data clearly indicated that exogenous hMSCs may develop into HuEPO-producing cells during culture in a growing embryo or host omentum, and that the new tissue is chimeric. Histochemical analysis demonstrated that approximately 30% of the EPO-producing cells were generated from hMSCs.

Physiological Regulation of Human Erythropoietin Production

To confirm that increased levels of EPO mRNA corresponded to elevated EPO protein in the serum, both host kidneys were removed to mask native EPO induction, and then anemia was induced by a rapid withdrawal of blood from the vena cava at a volume of 2% v/w body weight (*20*). Serum EPO levels were measured using RIA kit (Mitsubishi Kagaku Iatoron, Tokyo, Japan) 24 hr later, when EPO production peaks after the induction of anemia (data not shown). Rats with two functional kidneys were examined first as overall controls, and showed significantly elevated serum EPO levels in response to anemia induction. In contrast, the anephric rats with no organoid transplanted showed no change in serum EPO after induction of anemia, indicating that hepatic EPO production was insufficient to affect peripheral levels, whereas serum EPO levels were partially restored to significant levels in rats harboring an organoid (Fig. 2A). Notably, no significant difference in serum EPO levels was detected between the anephric rats with or without an organoid before anemia induction, strongly suggesting that EPO production by the organoid was not autonomous, but rather was suppressed in the absence of anemia. Because the RIA using the cross-reactive antibody to EPO could not distinguish human and rat EPO, we conducted real-time polymerase chain reaction experiments using a human-specific probe and primer to confirm that HuEPO was truly elevated in response to anemia induction. The TaqMan MGB probes and primers for HuEPO were designed by Primer Express Software (version 3.0, Applied Biosystems). The primers and the probe sequences were as follows: HuEPO-forward, 5′ AGC CCA GAA GGA **AGC CAT CT** 3′; HuEPO-reverse, 5′ GCG GAA AGT **GTC** AGC AGT GAT 3′; hEPO TaqMan-MGB probe, 5′ FAM-CCC TCC AGA TGC **GGC CTC** AGC T-MGB 3′ (bold letters show the sequence differences between human and rat EPO). The human *BUBR1* gene, which is constantly transcribed, was used as a human cell-specific endogenous control (*21*). The TaqMan probe and primers for human *BUBR1* were assay-on-demand gene expression products (Applied Biosystems assay identification number Hs00176169_m1). The sets of human-specific TaqMan probes and primers were not cross-reactive with rat EPO or rat BUBR1. Relative amounts of human-specific EPO cDNA were estimated by its amount relative to the amount of BUBR1 cDNA. Relative ratios of HuEPO to endogenous mRNA were compared before and after anemia induction (n=8 in each group). Human-specific EPO production was indeed enhanced by anemia induction (43.39%±2.36% no anemia vs. 66.77%±2.39%+anemia; $P=0.0043$). These data suggested that HuEPO producing cells are responsive to anemia.

Physiological Activity of Human Erythropoietin Derived From Organoid

We next analyzed whether EPO produced by the organoid reached sufficient physiological levels to affect the recovery from induced anemia. As the anephric rat died within 3 days, we generated a second group of experimental rats (Wister/Kyoto, Charles River, Yokohama, Japan) to address this issue. Native EPO production in these rats with or without organoid was suppressed by induction of nephritis with

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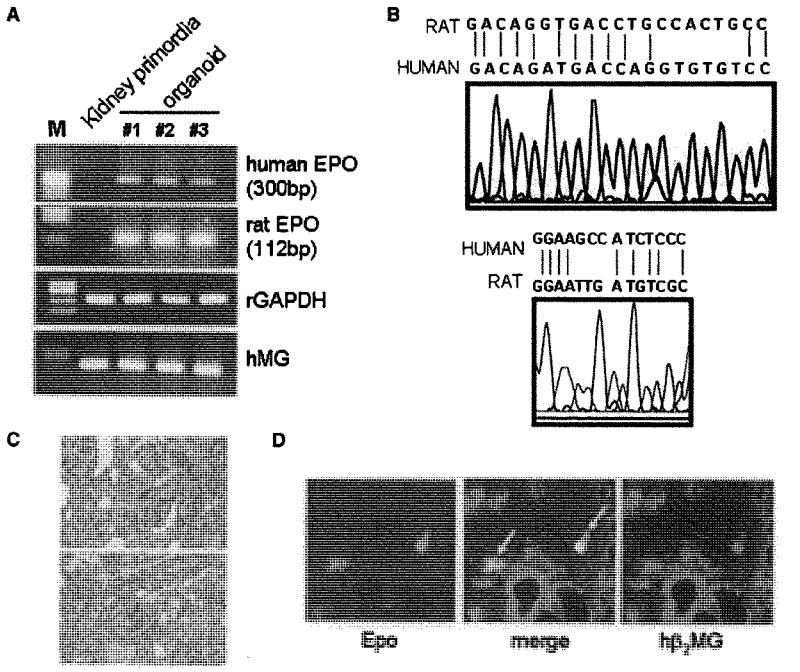

FIGURE 1. Production of human erythropoietin (HuEPO) from organoid derived from human mesenchymal stem cells (hMSCs). (A) The organoid was established from hMSCs using the modified relay-culture system. RNA was extracted, and the expression of human and rat EPO mRNA was examined by RT-PCR as previously described (*23, 24*). (*Lane 1*) Marker (ϕx174/HaeIII); (*lane 2*) kidney primordia before transplantation into omentum; (*lanes 3–5*) established organoid from three individual experiments. Expression of human-specific β_2 microglobulin (hMG) and rat-specific rGAPDH identified the chimerism of the organoid (*11*). (B) Nucleotide sequences of each RT-PCR product were analyzed to confirm that they contained unique sequences for human (upper panel) and rat (lower panel) EPO DNA. (C) EPO expression in the organoid was analyzed by immunohistochemical analysis using anti-HuEPO antibody. Yellow arrows indicate EPO-producing cells. Experiments were performed in quadruplicate and two representative micrographs are shown. (D) Double staining using HuEPO antibody (green) and human-specific β2-microglobulin (hβ2MG, magenta) indicate that HuEPO-producing cells are derived from hMSCs. Overlap of green and magenta is shown in white. Experiments were performed in quadruplicate and two representative micrographs are shown.

heminephrectomy. Two weeks later after the surgery of implantation of kidney rudiment and heminephrectomy, the rats were injected with anti-glomerular basement membrane antibody to induce nephritis as previously described (*22*), and then another 2 weeks later, anemia was induced. Histological analysis showed renal crescent formation and severe interstitial damage with suppressed potential for EPO production in the doubly treated rats (nephritis and heminephrectomy; Supplementary Fig. 2, available for viewing online only). Because EPO production peaked within 24 hr after anemia induction in each group, the amount produced by the doubly treated rats was sufficient to recover anemia within 10 days. We thus compared the kinetics of recovery from anemia in anephric rats with or without organoid. Normal kinetics of recovery from anemia was also established in age-matched rats with native kidney and without organoid. The time course of recovery from anemia in the EPO-suppressed rats was much slower than in control rats with both kidneys. In comparison, and importantly, native EPO-suppressed rats that harbored an hMSC-derived organoid in their omentum

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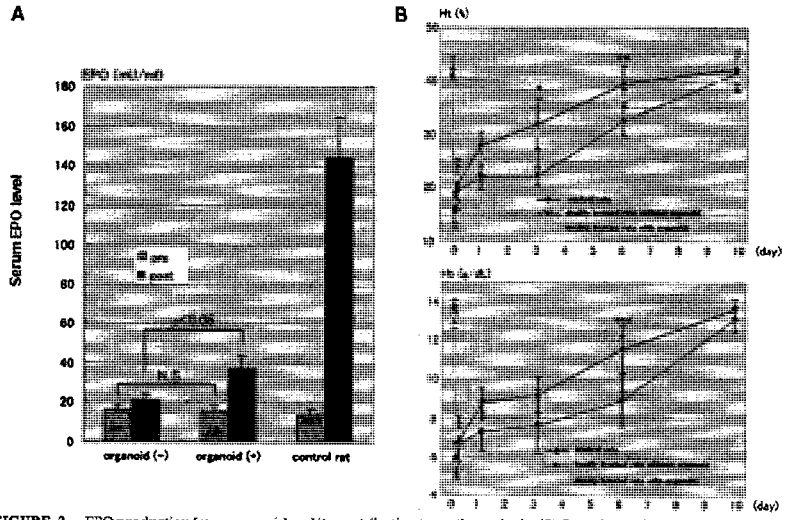

FIGURE 2. EPO production from organoid and its contribution to erythropoiesis. (A) Anemia was induced in the anephric rats with or without the organoid implanted in the omentum (n=8 each group). Serum EPO levels were subsequently measured by RIA. As a control, EPO levels were measured in anemia-induced rats retaining both native kidneys (n=8). (B) Anemia was induced in a second group of rats with their EPO production from the native kidneys minimized by glomerular basement membrane (GBM)-induced nephritis and heminephrectomy. Recovery from anemia in these doubly treated rats with or without the EPO-generating organoid was analyzed by hematocrit (Ht) levels (*upper panel*, n=30 in each group) and hemoglobin (Hb) levels (*lower panel*, n=4–30 in each group). Rats with both native kidneys induced for anemia were used as controls (n=34). (*P=0.033; **P=0.072, ***P=0.012 between rats with and without organoid, respectively).

exhibited a similar rate of recovery from induced anemia to control rats (Fig. 2B). Although renal anemia in humans is more chronic compared with the acute insult we examined here, these data suggest that the organoid-derived EPO production was physiologically functional in response to induced anemia. We are currently establishing a system whereby unnecessary EPO-producing cells can be eliminated using a suicide gene under the control of an inducible promoter.

CONCLUSION

We report three major findings from establishing hMSC-derived organoid in rats: (1) HuEPO is produced in rats harboring an organoid derived from autologous human bone marrow cells; (2) HuEPO production is stimulated by induction of anemia, suggesting that this system preserves the normal physiological regulation of EPO levels; and, (3) levels of EPO generated by the organoid in response to anemia are sufficient to restore red cell recovery in rats suppressed for native EPO production to a rate similar to that of control rats.

The results presented here have promising implications for developing effective therapies. Use of a transplantable organoid derived from hMSCs would eliminate the need for immunosuppressants if transplanted in the omentum of a patient from whom the bone marrow stem cells were isolated, thus addressing one of the major obstacles (tissue rejection) of such therapies. This work could spurn a new generation of therapy modalities for renal anemia.

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Research Articles

Olfactory Mucosal Autografts and Rehabilitation for Chronic Traumatic Spinal Cord Injury

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Abstract

Background/objective. Basic science advances in spinal cord injury (SCI) are leading to novel clinical approaches. The authors report a prospective, uncontrolled pilot study of the safety and outcomes of implanting olfactory mucosal autografts (OMA) in 20 patients with chronic, sensorimotor complete or motor complete SCI. *Methods.* Seven paraplegic and 13 tetraplegic subjects (17 men and 3 women; 19-37 years old) who sustained a traumatic SCI 18 to 189 months previously (mean = 49 months) were enrolled. Preoperative rehabilitation that emphasized lower extremity stepping using either overground walking training or a robotic weight-supported treadmill training was provided for 25 to 39 hours per week for a median of 4 months at 3 sites. No change in ASIA Impairment Scale (AIS) motor scores for the lower extremities or AIS grades of completeness was found. OMAs were transplanted into 1.3- to 4-cm lesions at C4-T12 neurological levels after partial scar removal. Therapy was continued postoperatively. Preoperative and postoperative assessments included AIS scores and classification, electromyography (EMG) of attempted voluntary contractions, somatosensory evoked potentials (SSEP), urodynamic studies with sphincter EMG, spinal cord magnetic resonance imaging (MRI), and otolaryngology and psychology evaluations. The Functional Independence Measure (FIM) and Walking Index for Spinal Cord Injury (WISCI) were obtained in 13 patients. *Results.* All patients survived and recovered olfaction. One patient was rehospitalized for aseptic meningitis. Minor adverse events occurred in 4 others. The mean duration of follow-up was 27.7 months (range = 12-45 months). By MRI, the lesion site was filled in all patients with no neoplastic overgrowth or syringomyelia. AIS grades improved in 11 of 20 patients, 6 (A → C), 3 (B → C), and 2 (A → B), and declined in 1 (B → A). Improvements included new voluntary EMG responses (15 patients) and SSEPs (4 patients). Scores improved in the FIM and WISCI (13/13 tested), and urodynamic responses improved in 5 patients. *Conclusion.* OMA is feasible, relatively safe, and possibly beneficial in people with chronic SCI when combined with postoperative rehabilitation. Future controlled trials may need to include a lengthy and intensive rehabilitation arm as a control.

Keywords

spinal cord injury, human, transplant, olfactory mucosa, regeneration, olfactory ensheathing cells, neural stem cells, rehabilitation

Introduction

Advances from experimental animal research are translating into clinical trials using stem cells and other cells/tissue for severe spinal cord injury (SCI), a condition previously thought to be hopeless. The olfactory mucosa contains neural stem cells (NSCs) and olfactory ensheathing cells (OECs).[1-4] Rats with complete or partial spinal cord transections demonstrate functional improvement after transplant of olfactory mucosa,[5] olfactory mucosa–derived NSCs,[6,7] or olfactory mucosa–derived OECs.[8-10] Because olfactory mucosa contains SCI repair–promoting cells (NSCs and OECs) and is readily accessible with minimally invasive techniques,[11,12] a human pilot clinical study was done to determine the safety and feasibility of olfactory mucosa autografts (OMAs) in severe, chronic traumatic SCI.[12] We

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found that the OMA procedure was safe and feasible. Two of 7 subjects improved from ASIA Impairment Scale (AIS) grade A to C. Interpretation of results was limited by the small number of patients and the lack of a control group. The potential improvement of these 7 OMA patients was constrained by the lack of an intense rehabilitation program and uncertainty about the optimal type of rehabilitation. We hypothesized that 3 components are critical for functional improvement after complete SCI: (*a*) OMA containing NSCs, (*b*) graft site management, and (*c*) an intense rehabilitation program.

First, olfactory mucosa is believed to be an ideal graft for SCI because it can be acquired autologously with minimally invasive techniques, and pieces large enough to fill a 3- to 4-cm cavity can be obtained. Using a person's own olfactory tissue may allow NSCs to integrate in a controlled manner without rejection or tumor formation that limits embryonic stem cell use. Unlike mesenchymal cells, Schwann cells, and OECs used for chronic SCI,[13-15] the normal course of the olfactory mucosa NSCs includes neurons. In fact, the olfactory system has the fastest rate of neurogenesis in the adult nervous system.

Second, the graft site must be modified before the graft is implanted. Preparing the injury site for grafting is in some cases technically challenging and may require several hours of surgery. The scar varies in composition (astrocytic, fibrotic, or mixed) and thickness.[12,16,17] Large cysts, multiple small cysts, or no cysts may be present. It is necessary to partially remove the scar superiorly and inferiorly to allow for transplant integration and bridging. In some cases only scar tissue remains at the injury site and must be removed.

Third, extended intense rehabilitation may be essential for recovery to strengthen physical components such as the skeletal, muscular, and vascular systems and to remodel the neural circuitry. It was unclear at the start of this study as to what would be the most effective rehabilitation program to promote recovery after NSC therapy. Repetition of unskilled movements,[18,19] strength training,[20] or exercise training[21,22] alone is not sufficient to induce motor map reorganization that is crucial to functional improvement after injury. In fact, SCI results in a disconnection syndrome that not only severs brain–spinal cord connections but also circuitry all over the neuraxis (eg, cortex–pons).[23] The rehabilitation that seemed to be the most effective in combination with OMA was overground ambulation, called BIONT (brain-initiated overground nonrobotic/nonweight supported training), which allows compensatory or novel walking patterns. Body weight–supported treadmill training (BWSTT) has also been considered as a potential therapy.

The main objective of the study is to determine the safety and efficacy of OMA in an additional 20 patients with chronic, severe SCI in humans enrolled at 1 of 3 different rehabilitation programs, which allowed us to compare BIONT with robotic BWSTT for intensive training.

Materials and Methods

Patient Selection and Inclusion Criteria

This phase I/II nonrandomized, noncontrolled prospective open-label study was approved by the Ethics Committee of the Hospital Egas Moniz, Centro Hospitalar de Lisboa Ocidental, Lisbon, Portugal, and meets the requirements of national agencies and ethical standards. All procedures were performed after obtaining written informed consent. Written consent included permission to culture and analyze a biopsy from the tissue to be grafted. Patients were fully aware of the experimental nature of the treatment, unclear outcomes, and possible side effects such as pain, spasticity, autonomic dysreflexia, worsening of motor or sensory function, infection, and unforeseen adverse events.

Patients were selected among individuals who had an SCI more than 1 year previously, were chronically paraplegic or tetraplegic, and were referred by Portuguese and Italian rehabilitation centers that specialize in the treatment of people with SCIs between April 2003 and December 2006 (Table 1). Costs for surgery and rehabilitation were paid by their respective governments. The rationale for selecting chronic (more than 12 months) SCI patients was to circumvent spontaneous recovery bias.

The inclusion criteria were the following: grade A or B on the AIS, age ≥18 and ≤40 years, presence of a cervical spinal cord lesion ≤3 cm or thoracic spinal cord lesion ≤4 cm, absence of significant nasal and paranasal sinus pathology, and absence of additional serious medical problems, brain disease, or psychological disturbance.

Twenty patients were enrolled in the study (17 men and 3 women). The mean age of the patients was 30.2 ± 5.7 years. Demographic data and clinical and imaging/radiological characteristics of the patients are presented in Table 1. Lesions resulted from road traffic accidents in 14 patients, sports accidents in 4, and work-related accidents in 2 patients. Lesions varied between 1.3 and 4 cm in the maximum vertical axis as measured on both the T1 and T2 weighted magnetic resonance imaging (MRI). Fifteen patients were AIS grade A, and 5 patients were AIS grade B. One patient (patient 12) was accepted with low SCI because a recent publication showed reversal of severely denervated muscle after electrical stimulation.[24] Transplants were done from 18 to 189 months after injury (mean = 49 months). Sham operations were not considered because of the difficulty of ethical justification as this would entail an increased risk for the placebo group.[25]

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Table 1. Demographic, Clinical, and Neurological Features of the Patients

Patient	Sex	Age (Years)	Months Post-SCI	SCI Level	P/T	Length of Lesion	AIS Grade
1	Male	31	43	C8	T	2.5	A
2	Female	21	20	T5	P	2.0	A
3	Male	26	18	C4	T	2.0	A
4	Male	37	20	C4	T	3.0	A
5	Male	33	189	C7	T	1.3	B
6	Male	20	52	C5	T	1.5	A
7	Male	34	123	T6	P	2.0	A
8	Male	27	28	C5	T	1.5	B
9	Male	22	33	T6	P	2.0	A
10	Male	24	28	T5	P	4.0	A
11	Male	35	35	T6	P	4.0	A
12	Male	30	60	T12	P	3.0	A
13	Male	31	24	C6	T	2.5	A
14	Male	24	43	C6	T	3.0	B
15	Female	37	101	C6	T	2.5	B
16	Male	23	38	C4	T	3.0	A
17	Male	33	40	C4	T	1.8	A
18	Male	25	27	C4	T	3.0	A
19	Male	30	32	T9	P	2.5	A
20	Female	19	33	C4	T	2.5	B

Abbreviations: SCI, spinal cord injury; P, paraplegic; T, tetraplegic; C, cervical; T, thoracic; AIS, ASIA Impairment Scale.

Operation

Briefly, pieces of olfactory mucosa were removed, cut in small pieces, and grafted into the spinal cord lesion site after performing a laminectomy. The detailed protocol for transplantation and surgical procedure has been reported previously.[12] Microbiological examinations of the nasal cavities were performed routinely before and at the beginning of the operation. Specimens of the olfactory mucosa graft and scar tissue removed from the spinal cord were examined for histopathological and immunocytological purposes. In 6 cases, the olfactory mucosa graft specimens were cultured to derive NSCs.

Preoperative and Postoperative Rehabilitation

All patients had preoperative rehabilitation (31.8 ± 6.8 h/wk with a mean duration of 34.7 ± 30 weeks) and postoperative rehabilitation (32.7 ± 5.2 h/wk with a mean duration of 92 ± 37.6 weeks). The preoperative rehabilitation was carried out up to the time immediately prior to the operation (maximum 7-day delay). Baseline measures were determined after the preoperative rehabilitation, which was intended to ensure a stabilized neurological status. The rehabilitation included physical therapy strategies for encouraging motor function at and below the lesion, enabling walking training as soon as possible. The rehabilitation program at all 3 centers consisted of the following: 2 hours of passive, assisted range of motion and strengthening exercises; 2 to 3 hours of functional training for balance, posture, standing, and transfers; and 2 to 3 hours of pregait and gait activities. With regard to the walking training strategies, the Centro de Medicina de Reabilitação Rovisco Pais (RP), Tocha, Portugal, rehabilitation center focused on robotic-assisted bodyweight-support treadmill training (BWSTT, Lokomat) for subjects 2 to 6, 8, and 11; and the Serviço de Medicina Física e de Reabilitação do Hospital S. Sebastião (SS), Feira, Portugal (subjects 1, 7, 9, 10, and 12) and Centro Giusti (CG), Florence, Italy (subjects 13-20) rehabilitation centers performed BIONT. BIONT is an assisted overground walking training, with loading on the hips, knees, and feet to promote sensorimotor biofeedback. There is freedom of movement (unrestricted by braces and other rigid bodyweight suspension systems) to allow the development of new, atypical motor patterns that may induce functional connections with supraspinal centers. BIONT focuses on the affected and nonaffected parts of the body.

Outcome Measures

Safety and efficacy measures are presented in Table 2. Any improvement in the AIS grade scale or in the lower extremity motor scores is considered as evidence for true gains because motor scores were 0 in the legs of patients after preoperative rehabilitation.

Preoperative and postoperative assessments included the AIS neurological exam as described in International Standards for Neurological and Functional Classification of Spinal Cord Injury Patients[26]; standard electromyography (EMG) after asking the subject to move particular muscles

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Table 2. Outcome Measures

Safety Measures	Efficacy Measures
Mortality	Ability to improve AIS grade
Incidence of complications	Variation in the ASIA scores
Readmission rate	Percentage of patients recovering deep anal sensation
Percentage of patients with worsening in the ASIA scale grade	Percentage of patients recovering anal sphincter control
Percentage of patients not recovering olfaction	Percentage of patients recovering bladder sensation
	Percentage of patients recovering bladder sphincter control
	Variation in the FIM measures
	Variation in the WISCI measures

Abbreviations: AIS, ASIA Impairment Scale; FIM, Functional Independence Measure; WISCI, Walking Index for Spinal Cord Injury.

and somatosensory evoked potentials (SSEP, cortically recorded after tibial nerve stimulation); urodynamic studies; full spinal cord MRI scan; otolaryngological evaluation including a general ear, nose, and throat examination, nasal endoscopy, olfactory evaluation, and computed tomography (CT) scan of the nose and paranasal sinuses; and psychological assessment. Psychological testing aimed to detect conditions such as active psychosis, major depression, anxiety disorder, severe mood disorder, suicidal behavior, alcohol addiction, drug addiction, low cognitive resources, and unrealistic expectations about treatment results.

All preoperative and postoperative neurological assessments were done unblinded in each rehabilitation center by the same trained SCI clinician and scheduled prior to OMA. The assessors were trained specifically for AIS (ASIA) assessments.[27] To reduce bias, the transplanted patients and the other SCI patients treated in each center were assessed in the same sessions. Eurotrials Scientific Consultants (Lisbon, Portugal) collected and analyzed data from each center.

The patients from rehabilitation centers SS and CG were also assessed for Functional Independence Measure (FIM)[28,29] and Walking Index for Spinal Cord Injury[30] (WISCI) scales. Pain was assessed via interviews asking the patients to identify painful areas, to describe the pain using standard descriptors, and to identify temporal aspects of pain. Spasticity was evaluated clinically. Neurological status of the patients was evaluated every 6 months after OMA. The mean duration for follow-up was 27.7 months (range = 12-45 months) postoperatively.

Statistical Analysis

The statistical power consideration given the sample size limitation (N = 20) required implementation of nonparametric exact tests rather than asymptotic parametric tests. Nonparametric Wilcoxon signed rank test was employed to test the existence of any statistically significant difference between premeasures and the last nonmissing postmeasurement values. The decision on the statistical significance of the findings was made using an α level of .05.

Results

Safety Issues

There was no mortality in our series. All the patients recovered olfaction during the follow-up, 95% of them within 2 months. Five patients experienced adverse events resulting from the treatment. Three of these patients had minor complications that resolved spontaneously (subcutaneous collection of cerebrospinal fluid along the incision) or with simple treatments. One patient developed a late (1 year) irritable bowel syndrome that required dietary changes and medication.

One patient (patient 8) had a more severe complication requiring hospital readmission. He developed aseptic meningitis 2 weeks after surgery, associated with sensory and motor neurological deterioration, changing the AIS grade from B to A. MRI imaging showed evidence of spinal cord edema. The acute manifestations subsided in 3 weeks with vancomycin and dexamethasone. The patient recovered to AIS grade B in 2 months, but sensory status only partially recovered. This was the only patient who had a reduction in AIS grade.

Efficacy

AIS assessments. The data obtained using the AIS and ASIA scores are summarized in Tables 3, 5, 6, 7, and 8. The estimated mean change was statistically significant ($p < .01$, Table 4) in all the neurological measures (motor arms, motor legs, light touch, and pin prick scores). The changes were assessed between the baseline and the last evaluation (28 ± 11 months). Eleven (55%) patients improved their AIS grades: 6 patients from grade A to grade C, 3 patients from grade B to grade C, and 2 patients from grade A to grade B (Table 3). Nine (45%) of the patients who scored 0 at baseline for lower extremities improved from 4 to 22 at the last evaluation, including distal segmental muscles exceeding 3 motor segments (Table 6).

Rehabilitation centers that focused on BIONT therapy (SS and CG) had patients with better motor recovery compared with the rehabilitation center that focused on BWSTT (RP; Figure 1).

Of the 15 patients without anal sensation at the baseline evaluation, 9 had recovered at the last follow-up: 5 patients in the first 12 months and the others later. Additionally, 6 ASIA grade A patients (patients 1, 7, 9, 10, 12, and 19)

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Table 3. Summary of AIS Grades

Patient	Baseline	Postsurgery AIS Grade					
		6 Months	12 Months	18 Months	24-30 Months	36-48 Months	LOCF
1	A	A	B	C	C	C	C
2	A	A	A	A	—	—	A
3	A	A	A	A	A	—	A
4	A	A	A	A	A	—	A
5	B	C	C	B	B	—	B
6	A	A	A	A	A	—	A
7	A	A	A	B	C	—	C
8	B	A	A	A	—	—	A
9	A	B	C	C	C	—	C
10	A	A	A	A	B	—	B
11	A	A	A	A	—	—	A
12	A	A	B	C	—	—	C
13	A	A	A	A	A	C	C
14	B	B	B	B	C	C	C
15	B	A	A	B	C	C	C
16	A	A	A	A	A	A	A
17	A	A	A	A	A	B	B
18	A	A	A	A	A	—	A
19	A	A	C	—	—	—	C
20	B	B	C	—	—	—	C

Abbreviations: AIS, ASIA Impairment Scale; LOCF, last observation carried forward; —, no evaluation done.

Table 4. Summary of Outcome Measures

	Pre ± SD	Post ± SD	Post–Pre	N	Z
ASIA motor arms (tetraplegics)	19.0 ± 14.5	23.5 ± 13.3	4.54	13[a]	−2.59
ASIA motor legs	0	4.95 ± 7.1	4.95	20[a]	−2.67
Paraplegics	0	9.3 ± 8.8	9.3	7	
Tetraplegics	0	2.6 ± 4.9	2.6	13	
ASIA light touch	42.7 ± 19.5	60.7 ± 28.0	18.0	20[a]	−2.82
Paraplegics	56.4 ± 10.5	80.0 ± 20.6	23.6	7	
Tetraplegics	35.4 ± 19.5	50.4 ± 26.5	15.0	13	
ASIA pin prick	38.9 ± 19.3	54.6 ± 29.8	15.75	20[a]	−2.8
Paraplegics	56.1 ± 10.7	77.4 ± 22.3	21.3	7	
Tetraplegics	29.6 ± 16.4	42.4 ± 26.3	12.8	13	
WISCI	0.15 ± 0.38	7.3 ± 2.6	7.15	13[b]	−3.19
Paraplegics	0	9.6 ± 1.5	9.6	5	
Tetraplegics	0.3 ± 0.5	5.9 ± 2.0	5.6	8	
FIM	71.8 ± 20.9	86.8 ± 25.9	15.0	13[b]	−3.18
Paraplegics	90 ± 12.2	110 ± 9.0	20.0	5	
Tetraplegics	60.5 ± 16.9	72.3 ± 21.8	11.8	8	

Abbreviations: SD, standard deviation; WISCI, Walking Index for Spinal Cord Injury; FIM, Functional Independence Measure.
[a]$P \leq .001$.
[b]$P \leq .01$.

recovered superficial sensation at S4-S5 segments. Five of the 20 patients without voluntary anal contraction recovered: 1 patient in the first 12 months and the others later. Of the 15 patients without bladder sensation at the baseline evaluation, 5 recovered the sensation of bladder fullness: 1 patient in the first 12 months and the others later. Only 1 of the 20 patients without bladder control recovered, by the 22nd month after surgery.

Functional and walking assessment. Thirteen patients from 2 rehabilitation centers (SS and CG) were assessed for functional studies. All the patients had improvements in FIM and WISCI scores (Figure 1). The mean FIM scores changed from 71 ± 23 at the baseline to 85 ± 28 at the last follow-up ($P < .01$). The WISCI scores changed from 0.2 ± 0.4 at the baseline to 7.4 ± 2.6 at the last follow-up ($P < .01$). WISCI scores were higher and achieved earlier in

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Table 5. ASIA Motor Arms—Tetraplegic Patients

Patient No.	Baseline	6 Months	12 Months	18 Months	24-30 Months	36-48 Months
1	46	48	50	50	50	50
3	9	11	11	8	8	
4	7	9	9	8	8	
5	48	48	48	48	47	
6	16	19	19	18	18	
8	20	16	18	18		
13	28	31	28		31	34
14	18	20	20			24
15	26	26	31	31		30
16	4	4	11			13
17	8	14	14			20
18	11	11	11	11	18	
20	6	10	18			
Mean	19	20.53	22.15	21.76	22.46	23.53
N	13	13	13	8	7	6

Table 6. ASIA Motor Legs

Patient No.	Baseline	6 Months	12 Months	18 Months	24-30 Months	36-48 Months
1	0	0	0	16	16	16
2	0	0	0	0		
3	0	0	0	0	0	
4	0	0	0	0	0	
5	0	1	2	0	0	
6	0	0	0	0	0	
7	0	0	0	0	14	
8	0	0	0	0		
9	0	12	12	20		
10	0	2	0	5	7	
11	0	0	0	0		
12	0	8	4	18		
13	0	6	0		6	8
14	0	0	0			4
15	0	0	0			6
16	0	0	0			0
17	0	0	0			0
18	0	0	0	0	0	
19	0	4	4			
20	0	2	0			
Mean	0	1.75	1.1	4.5	4.8	5.7
N	20	20	20	13	5	6

paraplegic than in tetraplegic patients ($P < .01$). There was no difference between paraplegic and tetraplegic patients in the gain in FIM scores ($P > .05$).

Hip flexor muscle recovery was observed initially at 13 ± 11 months (patients 1, 7, 9, 10, 12, 13, 14, 15, and 19). Knee and ankle muscle recovery was observed initially at 22 ± 7 months (patients 1, 7, 9, 10, 12, 13). This suggests a proximal-distal pattern of recovery.

Of the 13 patients assessed by functional studies, 1 paraplegic patient (patient 9) can ambulate with 2 crutches and knee braces with no physical assistance and 10 other patients can ambulate with walkers with or without braces with physical assistance. One tetraplegic patient (patient 13) ambulates with a walker, without knee braces or physical assistance.

Table 7. ASIA Light Touch

Patient No.	Baseline	6 Months	12 Months	18 Months	24-30 Months	36-48 Months
1	28	38	68	88	94	100
2	48	48	48	46		
3	14	14	14	12	14	
4	17	21	14	14	13	
5	78	69	59	44	72	
6	39	16	20	17	21	
7	52	56	64	72	90	
8	64	47	45	54		
9	52	66	84	92		
10	48	56	60	73	85	
11	53	56	56	56		
12	76	76	83	97		
13	24	37	32		50	70
14	46	62	62			60
15	51	51	40			75
16	15	15	37			41
17	27	41	41			42
18	26	26	26	26	29	
19	66	66	88			
20	31	34	64			
Mean	42.7	44.75	50.25	53.15	52	64.67
N	20	20	20	13	9	6

Table 8. ASIA Pin Prick

Patient No.	Baseline	6 Months	12 Months	18 Months	24-30 Months	36-48 Months
1	28	38	68	88	94	100
2	48	48	48	46		
3	15	14	14	12	12	
4	15	24	12	12	12	
5	71	54	43	35	56	
6	35	20	19	16	18	
7	52	56	64	72	90	
8	16	21	21	19		
9	52	66	88	100	104	
10	48	56	60	73	85	
11	51	48	54	54		
12	76	76	83	97		
13	22	32	32		35	40
14	42	34	34			64
15	49	49	46			72
16	15	15	32			31
17	24	39	39			39
18	25	25	25	25	32	
19	66	66	66			
20	28	34	56			
Mean	38.9	40.75	45.2	49.92	53.8	57.67
N	20	20	20	13	10	6

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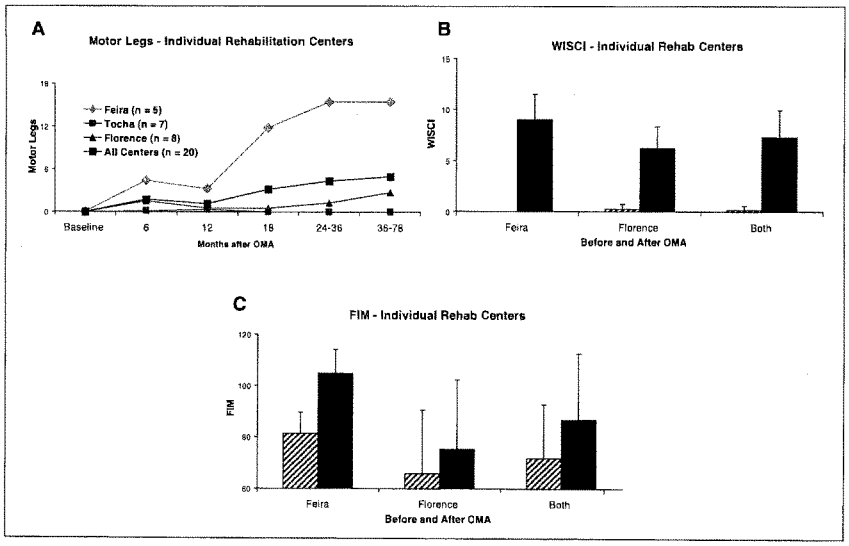

Figure 1. ASIA Motor Legs scores and WISCI and FIM after OMA with rehabilitation at individual centers. (A) ASIA motor legs scores at given times after OMA. After preoperative rehabilitation (mean = 8 months; range = 1-27 months), all 20 patients had a motor leg scores of 0. The greatest improvement after OMA was the primarily paraplegic patients receiving rehabilitation at SS (♦) with 5/5 patients improving, some improvement primarily in tetraplegics at GC (▲) with 4/8 patients improving, and no improvement (7/7 patients) in the primarily tetraplegics at RP (□). (B) WISCI scores (±SD) before OMA (cross-hatching) and after OMA (solid) with rehabilitation at SS and/or GC. (C) FIM scores (±SD) before OMA (cross-hatching) and after OMA (solid) with rehabilitation at SS and/or GC. WISCI, Walking Index for Spinal Cord Injury; FIM, Functional Independence Measure; OMA, olfactory mucosa autograft; SS, Hospital S. Sebastião, Feira, Portugal; CG, Centro Giusti, Florence, Italy; RP, Rovisco Pais, Tocha, Portugal.

Electrophysiological assessments. New voluntary activity in response to voluntary effort was documented by EMG in 15 (75%) of the patients. In 6 tetraplegic patients (patients 1, 6, 8, 13, 16, and 20) and in 5 paraplegic patients (patients 7, 9, 10, 12, and 19) voluntary motor potentials were found in lower limb muscles.

New SSEP findings by tibial nerve stimulation were recorded at a cortical level after tibial nerve stimulation in 4 patients (patients 2, 4, 14, and 16). An example of this activity is shown for RP patient 2 (see Figure 2).

Urodynamic studies. In 5 postoperative urodynamic studies, patients were now able to detect a full bladder (patients 1, 7, 9, 10, and 12). Particularly important are the result obtained in patient 9, with EMG evidence of sphincter voluntary contraction.

Magnetic resonance imaging. As in our previous study,[12] MRI showed a complete or almost complete filling of the lesion site in all patients, suggesting long-term graft viability. The grafted area has a "salt and pepper,"[12] "popcorn," or a mixed appearance. The "popcorn" appearance, a more heterogeneous and multiloculated pattern, is usually observed in the more chronic stage after the surgical treatment (Figure 3). There was no evidence of neoplastic tissue overgrowth or syringomyelia.

Pain and spasticity. Most of the pain reported in the study was musculoskeletal or surgical pain that resolved normally. One patient developed a late (1 year) irritable bowel syndrome, which could be also interpreted as a visceral neuropathic pain that subsided 5 years after surgery. No significant changes were observed in spasticity in the first weeks after surgery, as found in other studies.[31,32]

Spinal Cord Scar and Olfactory Mucosa Analysis

The most common observation was a scar of mixed composition containing astrocytic processes, fibroblasts, collagen, and laminin, with peripheral type axons interspersed, and single or multiple cystic cavities in different proportions.

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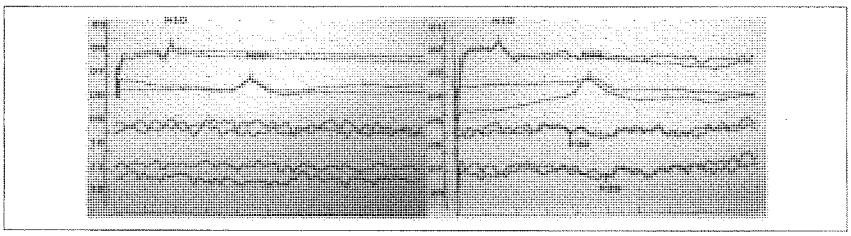

Figure 2. Somatosensory evoked potential findings (left = pre-OMA; right = Post-OMA). Recordings after tibial nerve stimulation of the new P30 (cervical) and P39 (cortical) waves 8 months after OMA in patient 2 (AIS grade A, T5 paraplegic patient, RP) in spite of no changes in AIS and ASIA scores. OMA, olfactory mucosa autograft; AIS, ASIA Impairment Scale.

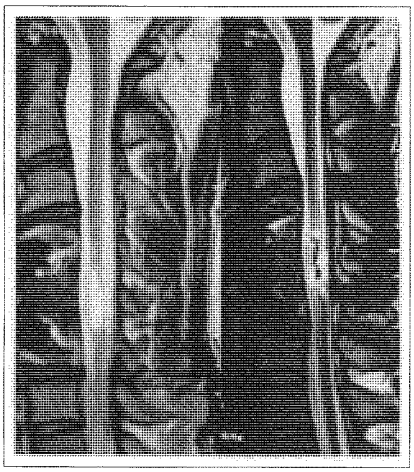

Figure 3. MRI findings. Left, preoperative T2-weighted sagittal MRI from patient 6 (AIS grade A, C5 tetraplegic patient) revealing a cystic lesion. Right, postoperative T2-weighted sagittal MRI from the same patient showing "popcorn" appearance in chronic stages. MRI, magnetic resonance imaging; AIS, ASIA Impairment Scale.

Very rarely neurons were found, and in many cases we observed macrophagic infiltration predominantly within the glial rather than the fibrotic component of the scar. In thoracic lesions, areas of collagen and peripheral type axons were marginally involved in astrocytic glial fibers, whereas in cervical lesions, a single cyst cavity lined by astrocytic glial scar with variable collagen content from the walls of surrounding vessels was found. In the most severe SCI cases, there was laceration of the dura mater, and the spinal canal was filled with bone fragments and large amounts of collagen, particularly in some thoracic patients.

Six of the olfactory mucosa biopsy samples were selectively cultured, and neurons were generated from the stem cells. Graft culture after dissociation of the olfactory mucosa biopsies revealed about 100 000 stem cells in each cubic millimeter of olfactory mucosa, which is the typical size of each piece of olfactory mucosa tissue implanted.[33] The number of pieces required to fill a cavity (generally more than 30) was dependent on the size of the cavity in the spinal cord after removing some of the scar tissue. *Methicillin-resistant Staphylococcus aureus* (MRSA) contamination was present in the olfactory mucosa graft biopsy from patient 8 even though the preoperative testing was negative.

Discussion

In this study, the safety and feasibility of OMA was supported. There was only 1 serious adverse event of aseptic meningitis. Close monitoring of patients using neurological, functional, and electrophysiological testing demonstrated indications of efficacy in a number of patients that seemed to relate to OMA combined with the BIONT rehabilitation program as opposed to OMA and BWSTT as the rehabilitation intervention.

AIS and ASIA Changes

After preoperative rehabilitation, 15 patients were AIS grade A and 5 were AIS grade B. Subsequent to OMA and postoperative rehabilitation, 11 (8 tetraplegics and 3 paraplegics) improved in AIS grade. Six improved by 2 grades and 5 by 1 grade. All the patients having rehabilitation at SS improved in AIS grade along with most of those who had rehabilitation at GC (primarily tetraplegic patients). No improvement was observed in AIS grade in the predominantly tetraplegic patients at RP receiving BWSTT. There

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were similar differences in the changes in ASIA scores. All patients had motor scores of 0 for the legs after preoperative rehabilitation, and there was no change in primarily tetraplegic OMA patients at RP, an average increase of 2.75 in the primarily tetraplegic OMA patients receiving therapy at GC, and a striking mean increase of 15.4 in the primarily paraplegic OMA patients at SS. No change was observed in motor arms in RP tetraplegic OMA patients; there was a mean increase of 8 in tetraplegic OMA patients at GC. Similar results depending on the rehabilitation center were found in sensory scores for light touch (LT) and pin prick (PP): RP: (LT = −.5.3; PP = −4.9), GC (LT = 22.9; PP = 16.1), and SS (LT = 42.8; PP = 44). The mean overall changes observed in ASIA scores are beyond the minimal detectable changes (motor = 0.29; sensory pinprick = 7.8; sensory light touch = 12.95) as recently reported.[33] Although results are striking at 2 of the centers using BIONT rehabilitation, functional changes are most important to the patients.

Functional Improvement

Functional changes were measured with urodynamic studies and WISCI and FIM scores. Bladder sensation or control can dramatically modify the quality of life of these patients. One patient recovered bladder control at almost 2 years after OMA, and 25% of the patients could now accurately detect when the bladder was full during urodynamic studies.

All the 13 patients in whom WISCI was measured demonstrated improvement. Slightly greater improvement was observed in the paraplegic patients, with the greatest improvement in patient 9, who went from no mobility to being able to ambulate 10 m with braces and crutches without assistance. The results are clinically relevant because they include recovery of motor voluntary activity in lower limbs, both proximal and distal, which are reflected by the gait improvements in a significant proportion of the patients. Although independent walking of a previous motor complete SCI patient might be an achievable goal, any recovery even with modest changes can have profound effects on the quality of life in the patients. This is particularly true in cervical SCI where individuals who can crawl by themselves provide some degree of locomotion independence in case of an emergency. There was a correlation between motor leg scores and WISCI (r = .69; n = 8). Because the patients were aware of their treatment, their motivation to improve their function, prevent immobility related side effects, and improve transfers may have been high.

The 13 who had FIM scores measured also improved, and the improvement correlated with their WISCI scores (r = .75; n = 13), motor arms (r = .83; n = 8), and motor legs (r = .75; n = 13). Again greater absolute improvement was observed in the paraplegic patients. Curt et al[34] found that some functional improvement as measured by Spinal Cord Independence Measure can occur in the first year after injury in complete SCI patients without concomitant changes in neurological condition or conductivity, so it was important to determine if there were any electrophysiological measures that point to neural repair.

Electrophysiological Evidence of Recovery

In 15 of the 20 patients, we demonstrated EMG activity in muscles on command below the level of injury, where previously no signal was present. This new voluntary control of muscles suggests that OMA had mediated a change across the injury site. This is further supported by the finding of SSEPs in some patients, objectively validating conductivity SCI repair.[34]

Safety Concerns and Adverse Events

A particular area of concern was the possibility of the introduction of pathogens in using a mucosa that is normally exposed to the air. We routinely perform preoperative and intraoperative microbiological examination of the nasal cavities and tissue graft. One of the 20 patients (patient 8) developed, 2 weeks after surgery, an aseptic meningitis syndrome (cerebrospinal fluid profile showed a high protein content and low glucose level, <100 cell count, predominant mononuclear cells, lymphocytes, and monocytes, with negative microbiological assays) and negative microbiological assay of blood, associated with MRI evidence of spinal cord edema and sensory and motor neurological deterioration. This patient had an intraoperative MRSA-positive nasal swab and graft examination (culturing required several days) following a negative preoperative microbiological evaluation. Secondary contamination due to surgical instrumentation when the graft passes through nasal pathways was suspected.

New visceral pain was present in 1 tetraplegic patient (patient 1) at 1 year postsurgery and interfered with daily activities. It was relieved with diet and medication (antidepressants and spasmolytics). It was strikingly postural dependent subsiding with recumbent position and was present during the current follow-up but subsided sharply 5 years after surgery. Because this patient was AIS grade A before OMA we do not know if this was associated with sensory and autonomic recovery or was due to maladaptive plasticity mechanisms after tissue transplantation.[35] The prevalence of pain in chronic SCI is high but the visceral one is low (5%).[36] Temporary musculoskeletal pain and spasm associated with physiotherapy efforts was present in several patients but neuropathic pain was not reported in any other patient.

Improbability of Spontaneous Recovery for Chronic, Complete SCI

Spontaneous late recovery is unlikely to be responsible for the gains reported because OMA was performed at least

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18 months or more after SCI. It is reported that only 5.6% of AIS A (32/571 patients) and 20.2% (23/114 patients) of AIS B improved in grade from year 1 to 5 after SCI.[37] In this study, 53.3% of AIS A and 60% of AIS B improved in grade. Because the 4 patients who improved the most in ASIA motor score for the legs (patients 1, 7, 9, and 12) had the OMA surgery performed more than 2 years after injury (3½,10, 2½, and 5 years, respectively), spontaneous recovery is highly improbable. This result also suggests that the time after injury is not a critical factor in performing the OMA procedure.

Rehabilitation Alone Insufficient for Recovery in Chronic, Complete SCI

One of the limitations of this study is that there was no control group with rehabilitation alone to separate the effects of rehabilitation and OMA and rehabilitation. However, 8/20 had about a year or more of intense rehabilitation before the OMA with no change in AIS grade, and their ASIA motor legs remained at 0. This strongly suggests that rehabilitation alone was not sufficient for these patients with complete SCI. Six of the 8 patients with a year or more of preoperative rehabilitation improved in AIS grade and had gains in ASIA motor leg scores (mean 13.5) subsequent to OMA and BIONT rehabilitation. Some recovery was present in 4 out of 6 of these patients at the 6-month evaluation after OMA. Again this suggests that the rehabilitation alone was not responsible for this recovery.

OMA Alone Insufficient for Recovery in Chronic, Complete SCI

OMA alone is not likely to be sufficient to improve function after a complete SCI. One of the important findings of this study is that rehabilitation, and possibly a particular type of rehabilitation program, has to be combined with OMA to get improvement. Although all rehabilitation programs probably greatly increase the health of the individual, functional gains as measured by the outcome measures used in this study and, most important, new voluntary muscle control were only observed in the BIONT groups at the SS and CG sites after OMA. No motor recovery was found in the robotic BWSTT program (RP), which primarily focused on the affected part of the body. For a OMA procedure performed in India, patients who were only given instructions to follow a rehabilitation program at home or at rehabilitation centers did not show any ASIA score improvement.[38] Their compliance and the intensity of therapy is unknown. The amount of recovery of OMA patients who received BIONT rehabilitation at SS and CG was also greater than the first 7 OMA patients we previously reported.[12] These findings stress the importance of not only combining OMA with rehabilitation but also that a BIONT-type rehabilitation program that focuses on the whole body may be necessary for improvement. The BIONT rehabilitation program is specifically goal directed at walking. Braces and support are minimized over time and load bearing is encouraged to achieve ambulation.[39,40] The use of muscle groups not normally used in walking is encouraged,[41] and the preinjury pattern of walking is not attempted. Other tissue/cell therapies, such as autologous bone marrow transplantation,[13,42] fibroblast growth factor,[43] and autologous Schwann cells,[14] for chronic complete SCI with no or other types of rehabilitation programs have not reported any improvements.

Recent studies in patients with chronic paraplegia confirm structural changes in the cerebral cortex and descending motor pathways including corticopontine tracts that are not directly connected to the spinal cord proving that the SCI represents a disconnection syndrome.[23] In SCI complete lesions, the creation of new neural pathways that mediate functional recovery require at least partial reconnection of anatomical circuits by scar removal and cellular transplantation strategies. Subsequent functional rewiring necessitates rehabilitation strategies to reorganize circuits in the brain and spinal cord for meaningful sensory–motor integration of new and/or remaining neural circuits[44-46] that may require a brain-initiated rehabilitation program such as BIONT.

Probable Mechanism of OMA Recovery

Other studies demonstrate that it is unlikely that long tract regeneration (eg, corticospinal tracts) takes place in the mature mammalian nervous system after SCI. In hemisectioned spinal cord, new axonal sprouting connections with propriospinal neurons proximal to the lesion site occur with formation of new intraspinal circuits relaying cortical input to distal locomotor centers.[47,48] Accordingly, both modified and new neural pathways may mediate recovery in incomplete patients and presumably in complete patients after successful cell/tissue therapies. It is unrealistic to expect a restoration of neural tissue function to its original state. A reconnection by a repair/bridge mechanism provided by immature neurons with assistance from other cell types such as OECs and fibroblasts could provide a lesion site neuronal network relay station between both the rostral and caudal stumps of the spinal cord. Support for this idea is that neurons developed from the 6 olfactory mucosa biopsy samples cultured from our patients. The new surgical injury may also induce plasticity.

OMA as Source of Neural Stem Cells

Stem cell treatment has the potential to be a major medical advance for SCI,[5,49,50] and several types of stem cells are available such as embryonic, fetal, umbilical cord blood cells, and adult stem cells (bone marrow mesenchymal cells, fat cells, brain subventricular zone, olfactory mucosa,

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and many other tissue types). Adult stem cells allow autologous transplants that avoid the problems of rejection, neoplasia,[51] disease transmission,[52-54] graft-versus-host disease,[55] and ethical issues. In contrast to other readily available sources of adult stem cells, the normal fate of olfactory mucosa stem cells is to become neurons and support cells. Olfactory mucosa NSCs maintain telomerase activity and low apoptotic activity after several years in culture, and unlike hematopoietic stem cells and bone marrow mesenchymal cells, the capacity to replicate does not change with a person's age.[56] The olfactory mucosa is the only part of the adult nervous system capable of lifelong neurogenesis and axogenesis[57] that is readily accessible.[11,12] Neurons in the olfactory mucosa are continually being replaced by newly formed neurons.[58,59] In culture, the olfactory mucosa is a source of stem cells that can become neurons,[1,3,4] including motoneurons[60] and oligodendrocytes.[61]

Other cell types in the olfactory mucosa may assist stem cell derivatives in bridging the injury site. OECs that are also present in the olfactory mucosa may contribute to the repair process. OECs obtained from the olfactory mucosa[8] promote axonal remyelination and regeneration in the damaged spinal cord. Equally favorable results were obtained using pieces of the lamina propria of the olfactory mucosa or cultured nasal OECs.[9,10] OECs derived from the olfactory mucosa express a unique combination of developmentally important proteins not reported in olfactory bulb OECs.[62] It also seems that adding other cells to OEC cultures such as fibroblasts[63] or meningeal cells might increase the efficacy in SCI regeneration.[64]

Theoretical Support for Scar Removal

The composition of the scar (astrocytic, fibrotic, or mixed) implies that it is a physical and molecular barrier to axon regeneration and neural circuitry repair. The thickness and sometimes huge expanse of scar tissue necessitates that before any cell bridging attempt, the scar should be surgically reduced to the point of not damaging normal tissue, which can be accomplished by careful microscopic dissection.

Future Directions

Our studies offer strong support for the safety and feasibility of the OMA procedure. There are clear indications of efficacy based on neurological, functional, and electrophysiological testing that justify moving forward to a larger, controlled clinical trial. However, there are 3 important points to consider:

1. The technical challenges of OMA mean that expansion to other sites with limited resources should be approached conservatively. Our team prepared for several years for this clinical study and proceeded slowly. Surgical techniques were perfected on cadavers. The nasal mucosa was examined in numerous cadavers to define the region where only olfactory mucosa is present. Given the complexity and invasiveness of the surgical procedure, the possibility of sham surgeries must be cautiously considered because of the risks involved.
2. New tests need to be developed for rapid recognition of olfactory tissue to prevent any respiratory tissue in the graft.
3. The OMA procedure must be combined with an intense rehabilitation program to obtain improvement. The design of a randomized controlled clinical trial will require 2 arms given our results. Prior to randomization, all subjects should receive an intensive and specific rehabilitation effort for up to several months. This phase will help reduce confounders of latent function that a rehabilitation effort may bring out.[65] One group would be randomized to continued rehabilitation and another group to the surgical procedure with OMA and rehabilitation. The specific rehabilitation intervention will require continued consideration, given the experience we describe with BIONT compared with robotic-assisted therapy. In addition, the effort at driving training-induced plasticity must be continued intensively for at least 2 to 3 years.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interests with respect to the authorship and/or publication of this article.

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Stem Cell Recipe for Astrocytes

26 May 2011

Researchers at the University of Wisconsin-Madison have cooked up a method to nudge pluripotent stem cells all the way to astrocytes. The new protocol, published online May 22 in Nature Biotechnology, means researchers can better model the astrocyte contributions to neurodegenerative diseases. Mimicking the natural developmental recipe for these star-shaped neuron supporters, the scientists created astrocytes that swallow glutamate, encourage synapse formation, and whip up a blood-brain barrier, just like the nature-made versions do.

Senior author Su-Chun Zhang and first author Robert Krencik, who studied in the Zhang lab but has since moved to the University of California, San Francisco, led the effort. Zhang, along with others, figured out how to turn stem cells into neurons nearly a decade ago (Zhang et al., 2001). But astrocytes have proved more elusive. With several studies pointing to astrocytes as participants in neurodegenerative diseases such as amyotrophic lateral sclerosis, researchers needed a way to grow their own.

Krencik used human starting material, either embryonic stem cell (ESC) or induced pluripotent stem cell (iPSC) lines. He applied standard protocols to shepherd them through the neuroepithelial and into the neural progenitor stage, then figured out how to make them into astrocytes. Three key factors allowed the group to succeed, Zhang told ARF: patience, chemically defined media, and regular disruption of clumped-together cells.

During human development, Zhang pointed out, astrocytes appear three months after neurons. Hence, the researchers waited out two months of culture, and at that point the progenitors started making more astrocytes than neurons.

Although serum works to feed and produce mouse astrocytes, it impedes the process in human cells, Zhang said. Again, natural biology provided the clue: "In the brain, you do not need serum," he said, adding that because of the blood-brain barrier, the brain actually "hates" serum. If the culture is contaminated with any cells that do prefer serum, he said, those cells could take over the population. Thus, carefully defined chemical media proved to be the way to go.

The progenitors tend to make neurons when clustered together, but are more likely to switch to glia when single cells float alone in suspension. Therefore, Krencik dissociated the cells in the growing cultures every week. Finally, he plated individual cells and added growth factors to help them continue developing as astrocytes. Adding particular growth factors produced different astrocyte subtypes.

To measure his success, Krencik looked for, and found, every astrocyte marker he could think of. Further, he checked that the cells can carry a current but do not produce action potentials as neurons do. Their glutamate receptors and transporters were operable, and they propagated calcium waves like proper glia do. When co-cultured with neural progenitors, the astrocytes nursed the formation of synapses between developing neurites.

In a final experiment, Krencik implanted the immature astrocytes into the lateral ventricles of

neonatal mice. The human cells not only survived, but also reached out to encircle blood vessels, suggesting they helped form the blood-brain barrier. The implanted cells lasted for at least six months, with no evidence of overproliferation or tumor formation, Zhang said.

François Berthod of the University of Laval in Québec, Canada, wrote in an e-mail to ARF that the functional test results were convincing. However, he noted, the researchers started with standard cell lines. What many researchers would like to do, and are already doing with neurons, is to use patient-derived iPSCs to make disease-specific cell lines for drug screening and other experiments (see ARF related news story). It remains to be shown that a person's cells, turned from fibroblasts to iPSCs to astrocytes, will still exhibit pathology, he wrote.

The study also shows that making these kinds of cell lines will be a slow process, said Nicholas Maragakis, who called the timeline "sobering." Maragakis works at the Johns Hopkins School of Medicine in Baltimore, Maryland. Obtaining statistically significant results will require hundreds of patient-specific cell lines. "It takes a long time to generate a cell line; that is something as a community we are going to have to face," he said.

Some scientists are already testing transplantation of stem cell-derived lines as a therapeutic for amyotrophic lateral sclerosis (see ARF related news story). Although he was careful to call astrocyte transplants "purely speculative," Berthod noted that the protocol might, in the future, allow doctors to collect a person's cells and create customized astrocytes for grafts.
—Amber Dance

COMMENTS

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Comments on News and Primary Papers

François Berthod
LOEX, Université Laval

Posted: 26 May 2011

Paper: Specification of transplantable astroglial subtypes from human pluripotent stem cells.
This work is very interesting because it shows that astrocytes can be successfully differentiated from human iPS cells (ES cells being less relevant, in my point of view). The paper is mostly oriented toward showing that astrocytes are functional. This is convincingly shown both in vitro and after graft in mouse brain.

Generating functional astrocytes from human iPS cells will be very valuable for fundamental studies to better understand their development and function in vitro and in vivo. However, the cells in this study were obtained from cell lines. To bring this technology to the study of ALS, this work needs to be done using the patient's cells. This should be quite feasible, starting from a small skin biopsy, to generate iPS cells from fibroblasts. The next step is more challenging: to show that the ALS phenotype of astrocytes (still largely unknown) will be re-expressed in these cells even though they derived from iPS cells. In other words, it is not clear at this point if a patient-derived fibroblast transformed into an iPS cell, and then differentiated into an astrocyte, will express the same disease characteristics than a native astrocyte from the patient's spinal cord. Demonstrating this re-expression of the ALS phenotype from iPS cells would be a major breakthrough.

Another potential approach could be a cell therapy, using the patient's own cells to generate iPS cells and astrocytes in order to graft back these autologous astrocytes in the patient brain or spinal cord. However, such an approach is purely speculative, since there is no clear evidence up to now that it could be beneficial, at least for ALS.

In conclusion, this work is an encouraging step in the long process to develop in-vitro models of ALS and, perhaps one day, a cell transplantation therapy (which is pure speculation today).

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Krencik R, Weick JP, Liu Y, Zhang ZJ, Zhang SC. **Specification of transplantable astroglial subtypes from human pluripotent stem cells.** *Nat Biotechnol.* 2011 Jun;29(6):528-34. PubMed.

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ARTICLES

nature biotechnology

Specification of transplantable astroglial subtypes from human pluripotent stem cells

Robert Krencik[1,2], Jason P Weick[2,6], Yan Liu[3,6], Zhi-Jian Zhang[2] & Su-Chun Zhang[1–5]

Human pluripotent stem cells (hPSCs) have been differentiated efficiently to neuronal cell types. However, directed differentiation of hPSCs to astrocytes and astroglial subtypes remains elusive. In this study, hPSCs were directed to nearly uniform populations of immature astrocytes (>90% S100β$^+$ and GFAP$^+$) in large quantities. The immature human astrocytes exhibit similar gene expression patterns as primary astrocytes, display functional properties such as glutamate uptake and promotion of synaptogenesis, and become mature astrocytes by forming connections with blood vessels after transplantation into the mouse brain. Furthermore, hPSC-derived neuroepithelia, patterned to rostral-caudal and dorsal-ventral identities with the same morphogens used for neuronal subtype specification, generate immature astrocytes that express distinct homeodomain transcription factors and display phenotypic differences of different astroglial subtypes. These human astroglial progenitors and immature astrocytes will be useful for studying astrocytes in brain development and function, understanding the roles of astrocytes in disease processes and developing novel treatments for neurological disorders.

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Astroglial cells are the most abundant cell type in the human brain and spinal cord and are now understood to be as important as neurons for brain function[1,2]. During development, astroglial progenitors are specified after neurogenesis, although their identity is not well defined owing to lack of reliable markers[3,4]. Astroglial progenitors differentiate to immature astrocytes, which are essential for the formation of functional synapses[5,6]. In the adult brain, mature astrocytes insulate synapses and remove excess transmitters, such as glutamate, released during neural excitation, thus preventing excitotoxicity[7]. Astrocytes are crucial for maintaining a homeostatic environment for the healthy brain by supporting neurovascular coupling at the blood-brain barrier, regulating blood flow[8] and supplying energy metabolites throughout the brain[9]. Abnormalities in astroglial cells are implicated in a number of human pathologies, including astrocytomas, epilepsy[10], Alexander disease[11] and neurodegenerative diseases[12,13]. Thus, understanding how to regulate the generation, maintenance and functions of human astroglial cells will likely benefit the treatment of a range of neurological injuries and diseases.

Astrocytes are heterogeneous in many respects, including morphology, growth rates[14], gene expression profiles[15,16], electrophysiological properties[17], gap junction coupling and calcium wave propagation dynamics[18,19]. However, how these various astroglial phenotypes are gained is largely unknown. In the mouse and chick spinal cord, homeodomain and helix-loop-helix (HLH) transcription factors are expressed in progenitors of specific dorsal-ventral domains, and genetic alterations of these factors shift the gene expression pattern of astrocytes generated from these domains[20–22]. This suggests that astroglial diversity may be determined through regional patterning (specification of regional identities) of progenitor cells. However, it remains unknown whether astroglial subtypes may be generated by simply patterning neural stem or progenitor cells, especially human stem cells.

In the present study, we describe a chemically defined differentiation system for efficient generation of immature astrocytes from hPSCs, including embryonic (hESCs) and induced pluripotent stem cells (iPSCs). HPSCs were first differentiated to neuroepithelial cells and specified to regional progenitors. They were then expanded as free-floating clusters or 'astrospheres' in the presence of growth factors, with periodic dissociation into single cells to promote gliogenesis. Astroglial differentiation from human neural stem cells or fetal tissues often requires serum, and the capacity to expand is limited. In contrast, the present technology allows generation of a nearly pure population of astroglial progenitors in a chemically defined system, which can be expanded to large quantities. Furthermore, the resultant cell population is free of immune cells such as microglia, and regionally and functionally specialized astroglial subtypes can be readily generated. We apply this approach to three different hPSC lines and show that it yields progenitors that can expand in culture for a long time, producing an estimated 2.8×10^{12} immature astrocytes at 6 months from one hPSC cell. Notably, we find that regionally and functionally distinct human astroglial subtypes are induced by patterning neuroepithelial cells at an early stage, and that they maintain their identities after transplantation into ectopic mouse brain regions, providing a possible cellular source for regenerative medicine.

RESULTS

Differentiation to astroglia follows developmental principles

Astroglial cells appear after neurons during vertebrate development. We hypothesized that hPSC-derived neural progenitors, after

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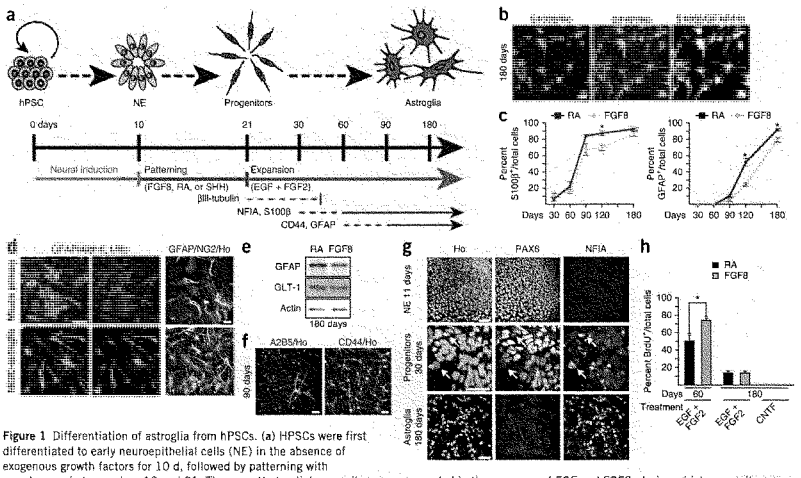

Figure 1 Differentiation of astroglia from hPSCs. (**a**) HPSCs were first differentiated to early neuroepithelial cells (NE) in the absence of exogenous growth factors for 10 d, followed by patterning with morphogens between days 10 and 21. The neural/astroglial progenitors were expanded in the presence of EGF and FGF2, during which progenitors were differentiated for 7 d with CNTF every 30 d for characterization with cell type–specific markers. RA, retinoic acid. (**b**) At day 180, immature astrocytes display a stellate morphology, express S100β in both the cytoplasm and nuclei, and express GFAP in a filamentous pattern throughout the cytoplasm. Nuclei are indicated by Hoechst (Ho) staining. (**c**) Temporal course comparison of S100β (120 d, $P = 0.0055$) and GFAP (120 d, $P = 0.001$; 180 d, $P = 0.0066$) expression of retinoic acid– and FGF8-specified astroglia (from three separate passages of the H9 hESC line) among total cells. (**d**) hESC-astroglia cells express Aldh1L1, but not NG2, in contrast to mouse primary astrocytes. (**e**) Western blotting analysis confirms the expression of GFAP and GLT-1 in day 180 astroglia (RA and FGF8, as in **c**). (**f**) Subsets of astroglia express A2B5, whereas the majority of immature astrocytes express CD44 by 90 d. (**g**) NFIA is not expressed in early neuroepithelial cells at day 11, but it begins to be expressed in a small number of progenitors with concomitant down-regulation of PAX6 at day 30 (arrows). By day 180, all cells express NFIA. (**h**) Incorporation of BrdU by retinoic acid– and FGF8-specified astroglial progenitors at 60 d ($n = 6$, $P = 0.0043$) demonstrates differential proliferation of subtypes. By 180 d, BrdU uptake is not different between groups, and is completely absent in cells after removal of growth factors and addition of CNTF. Scale bars, 50 μM. Data are represented as mean ± s.e.m. *, $P < 0.05$.

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temporal expansion, become gliogenic and generate astroglia under conditions that facilitate glial differentiation (**Fig. 1a**). HPSCs were directed to neuroepithelial cells, followed by differentiation to neural progenitors from days 10 to 21 in the presence of either the posterior patterning molecule retinoic acid (0.5 μM), or the anterior patterning morphogen fibroblast growth factor 8 (FGF8, 50 ng/ml)[23,24] to examine whether early specification leads to divergent astroglial subtypes (see below). Differentiation of day 30 retinoic acid–treated progenitors from the H9 hESC line showed that a small population of cells (7.7% ± 1.5) were S100β$^+$ and hardly any cells (<0.1%) were GFAP$^+$, the two common astroglial markers. Most other cells were shaped like columnar epithelial cells, indicative of progenitor identity, whereas some exhibited neuronal phenotypes and were positive for the neuron-specific marker βIII-tubulin (4.4% ± 0.8), which decreased over time. At increasing time periods, the number of S100β$^+$ cells continued to increase, and displayed the typical stellate morphology of astroglia (**Fig. 1b**,**c**). Similarly, GFAP-expressing cells began to appear after 8 weeks, and the percentages increased over time (**Fig. 1b**,**c**). The GFAP$^+$ cells always co-labeled with S100β. A similar progression of astroglial marker expression was observed in cells that were specified with FGF8, but considerably slower at certain time points (**Fig. 1c**). Aldh1L1, a recently identified marker for the astroglial lineage[25], but not NG2, a proteoglycan expressed by NG2 cells[26], was also detected in GFAP$^+$ cells (**Fig. 1d**). Western blotting analysis of day 180 immature astrocytes demonstrated the expression of GFAP and the astrocyte-specific glutamate transporter GLT-1 (**Fig. 1e**). These results further confirmed their astroglial identity. Leukemia inhibitory factor (LIF) had a similar effect as ciliary neurotrophic factor (CNTF) in increasing the proportion of GFAP$^+$ cells after treatment of the day 180 progenitors for 6 d (**Supplementary Fig. 1a**).

To identify progenitors during astroglial differentiation, we examined putative glial progenitor markers, including A2B5, CD44 (ref. 27) and NFIA[28]. A2B5 was expressed in a subset of S100β$^+$ cells at days 30 and 90 (9.8% ± 3.2 and 8.7% ± 2.1, respectively), and the percentage decreased as cells became GFAP$^+$. CD44, however, was not observed until day 60, and by day 90, 79.5 ± 1.9% of S100β$^+$ cells expressed CD44 (**Fig. 1f**). NFIA, which was completely absent in PAX6$^+$ neuroepithelial cells at day 11, began to be expressed by day 30 as cells downregulated PAX6. Day 180 astroglial cells all expressed high levels of NFIA (**Fig. 1g**). Thus, astroglial progenitors or immature astrocytes can be identified by expression of NFIA-S100β at 4–8 weeks after hPSC differentiation, and more mature astrocytes can be marked additionally by CD44-GFAP after 8–12 weeks of differentiation. This expression pattern is remarkably similar to that of *in vivo* human development[29,30].

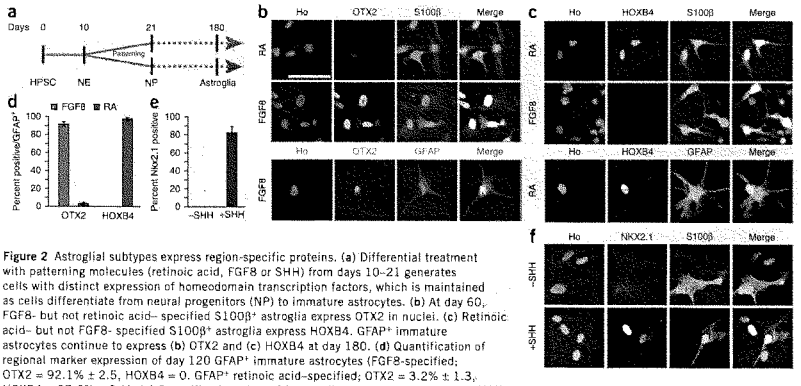

Figure 2 Astroglial subtypes express region-specific proteins. (**a**) Differential treatment with patterning molecules (retinoic acid, FGF8 or SHH) from days 10–21 generates cells with distinct expression of homeodomain transcription factors, which is maintained as cells differentiate from neural progenitors (NP) to immature astrocytes. (**b**) At day 60, FGF8- but not retinoic acid– specified S100β$^+$ astroglia express OTX2 in nuclei. (**c**) Retinoic acid– but not FGF8- specified S100β$^+$ astroglia express HOXB4. GFAP$^+$ immature astrocytes continue to express (**b**) OTX2 and (**c**) HOXB4 at day 180. (**d**) Quantification of regional marker expression of day 120 GFAP$^+$ immature astrocytes (FGF8-specified; OTX2 = 92.1% ± 2.5, HOXB4 = 0. GFAP$^+$ retinoic acid–specified; OTX2 = 3.2% ± 1.3, HOXB4 = 97.6% ± 2.1). (**e**) Quantification of day 30 ventralized astroglial progenitors (-SHH; NKX2.1 = 0. +SHH; NKX2.1 = 82.6% ± 7.0). (**f**) Day 60 S100β$^+$ astroglia differentiated from SHH-ventralized neural progenitors express NKX2.1. Scale bar, 50 μM.

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Quantitative reverse transcription (qRT)-PCR analysis indicated that the hPSC-derived day 210 astroglia expressed high levels of additional astroglial genes, including NF1X, CHL1, GLAST, GLT1 and aquaporin 4 (**Supplementary Fig. 1c**). Taken together, these results not only confirmed the astroglial identity but also suggested functional attributes of the hPSC-derived astroglia.

The hPSC-derived astroglial progenitors were expanded continuously for at least 8 months and survived freeze-thaw cycles. BrdU pulse-labeling for 10 h in day-60 progenitors revealed a higher percentage of cells undergoing DNA synthesis, a correlate of cellular proliferation, in FGF8-specified progenitors (74.2% ± 2.0, $n = 6$) compared to retinoic acid–specified progenitors (50.6% ± 6.1) (**Fig. 1h**). At 6 months, the extent of BrdU labeling decreased, the two groups exhibited a similar proliferation rate, and removal of growth factors inhibited DNA synthesis (**Fig. 1h**). In the presence of EGF and FGF2, the retinoic acid–specified astroglial progenitors maximally expanded at a rate of 7.6 ± 1.2 times every 6 d for 4–5 months when seeded at 24,000 cells/cm^2. Although hESCs and iPSCs exhibit slightly different efficiency in neuroepithelial cell generation[31], differentiation of neuroepithelial cells and expansion of astroglial progenitors from these various hPSC lines (H9, H7, (IMR90)-4) were similarly efficient. If one hPSC is differentiated to neuroepithelial cells, converted to glial progenitors and then expanded in suspension, an estimated 2.8×10^{12} immature astrocytes can be generated in 6 months, taking into account any cell loss during the procedure. Therefore, this method allows generation of large quantities of astroglia.

Regionally specified neuroepithelia generate astroglial subtypes

Like neurons, astrocytes in different regions of the central nervous system (CNS) exhibit different phenotypes. We hypothesized that regionally distinct astroglia may be specified from hPSCs in the same way as for neuronal cell types through patterning of neuroepithelial cells and subsequent differentiation (**Fig. 2a**). At day 30 of differentiation from H9 hESCs, nearly all of the cells patterned with retinoic acid during days 10–21 expressed the hindbrain/spinal cord-specific transcription factor HOXB4 (98.6% ± 0.7, $n = 5$) and very few expressed the midforebrain marker OTX2 (3.1% ± 0.8). The FGF8-treated cells, similar to those not treated with FGF8 (ref. 32), expressed OTX2 (95.4% ± 3.0) and none expressed HOXB4. This expression pattern of homeodomain transcription factors persisted as cells began to express astroglial markers S100β and GFAP (**Fig. 2b–d** and **Supplementary Fig. 2a**), but with a slight decrease of OTX2 in GFAP$^+$ astrocytes. A similar expression pattern of homeodomain transcription factors was observed in primary astrocytes isolated from the mouse embryonic brain and spinal cord (**Supplementary Fig. 2c**), and in astrocytes specified from iPSCs (**Supplementary Fig. 3**). qRT-PCR analysis confirmed differential expression of additional homeodomain genes and functional genes in the anterior and posterior immature astrocytes (**Supplementary Fig. 2b**), signaling potential functional diversities.

To determine whether astroglia with a dorsal-ventral distinction can also be specified, neuroepithelial cells were treated with or without the ventralizing factor sonic hedgehog (SHH, 500 ng/ml). In the absence of morphogens, hESC-derived neural progenitors exhibit a dorsal telencephalic phenotype[33]; none of the astroglial progenitors expressed the ventral marker NKX2.1 (**Fig. 2e,f**). In contrast, the majority of astroglial progenitors (day 30) differentiated from the SHH-treated neuroepithelial cells were labeled for NKX2.1, though NKX2.1 was noticeably decreased upon S100β expression (**Fig. 2f**). Regional marker expression was confirmed in subsets of GFAP$^+$ astrocytes in P1 mouse brain and spinal cord sections (**Supplementary Fig. 2d**). Together, our results indicate that region-specific astroglia can be specified from hPSCs in the same way as for region-specific neuronal types. The same trend of astroglial differentiation and regional patterning was observed with the H7 hESC line and the (IMR90)-4 iPSC line (**Supplementary Fig. 3a,b**).

HPSC-derived immature astrocytes are functional

In contrast to neurons, astroglia are described as passive cells because they cannot generate action potentials and their voltage-gated currents decrease during maturation[34]. Whole-cell patch clamp recordings of

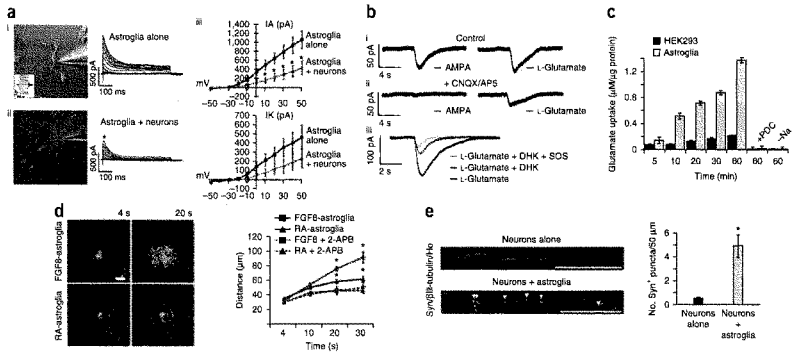

Figure 3 Functional characteristics of hPSC-derived immature astrocytes. (**a**) Immature astrocytes were analyzed by whole-cell patch clamping. (i–iii) Voltage steps (clamped at −70 mV and stepped from −50 to +50 mV at 10 mV increments for 500 ms) induced outward currents in red fluorescent–labeled 4-month astroglia, which significantly decreased in the presence of neurons for 2 weeks ($n = 10$ for both groups). Action potentials could not be elicited (inset in i). (**b**) (i–ii) The inward current response by AMPA was blocked with CNQX and AP5, and the L-glutamate response was partially reduced. (iii) L-Glutamate–induced inward current was reduced by glutamate transporter inhibitors DHK and SOS. (**c**) Kinetics of cellular uptake of L-glutamate (starting at 50 μM) was measured in the absence or presence of PDC and Na^+ and normalized to μg of protein ($n = 3$ for each group). (**d**) Immature astrocytes propagate calcium waves to adjacent cells upon mechanical stimulation. Calcium wave propagation was measured for anterior and posterior immature astrocytes (20 s; retinoic acid = 59.2 μm ± 3.2, FGF8 = 76.0 μm ± 3.1, $P = 0.0196$. 30 s; retinoic acid = 62.4 μm ± 3.8, FGF8 = 91.4 μm ± 7.8, $P = 0.0288$, $n = 3$ (arrowheads) for all groups), both of which were inhibited by 2-APB (20 s p values; retinoic acid = 0.0144, FGF8 = 0.0104. 30 s p values; retinoic acid = 0.0147, FGF8 = 0.0197). (**e**) Co-culturing of hESC-derived neurons and immature astrocytes for 3 weeks results in an increased presence of Synapsin 1+ puncta (Syn, $n = 3$, $P = 0.0119$). Scale bars, 50 μm. Error bars, s.e.m. *, $P < 0.05$.

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both retinoic acid–specified ($n = 18$) and FGF8-specified astroglia ($n = 10$, expanded for 120 d from line H9 and treated with CNTF for 7 d) displayed a voltage-dependent initial rapid outward current that was inactivated within 100 ms and a lower sustained current, and never displayed action potentials in current clamp. This passive electrophysiological property resembles that observed in immature primary mouse astrocytes[34]. To determine whether neuronal signaling promotes astroglial maturation, 120-d red fluorescent–labeled astroglia were cultured either with or without hESC-derived neurons (day 28) for 2 weeks (**Fig. 3a**). Co-cultured astroglia displayed a change in morphology and a significantly decreased transient outward current ($n = 10$ with and without neurons), suggesting maturation of astroglial cells *in vitro*.

One critical function of astrocytes is signaling and buffering of neurotransmitters released during neuronal excitation. To determine whether hESC-derived immature astrocytes contain functional glutamate receptors, we applied the glutamate receptor agonist AMPA or L-glutamate (100 μM) in the absence or presence of CNQX and AP5 (20 μM). An inward current was activated upon addition of AMPA, which was completely blocked in the presence of CNQX and AP5 (retinoic acid–specified, $n = 5$; FGF8-specified, $n = 5$) (**Fig. 3b**). In contrast, the L-glutamate response was partially blocked. L-glutamate induced a large inward current in all cells tested (retinoic acid–specified, $n = 8$; FGF8-specified, $n = 8$). 100 μM of D,L-aspartate produced a similar inward current (not shown). When the GLT-1–specific inhibitor dihydrokainate (DHK, 100 μM) was applied to the same cells for 1 min before L-glutamate administration, the inward current was substantially smaller, suggesting that glutamate-induced inward currents depend on the function of glutamate transporters. Addition of the general glutamate transporter blocker L-serine-*O*-sulfate (SOS, 100 μM) further decreased the current (**Fig. 3b**). No significant differences in induced currents were observed between the two subtypes of immature astrocytes owing to the high variability of peak currents between cells. Furthermore, hESC-derived immature anterior astrocytes were competent to take up glutamate from media over time at a higher rate than that of HEK293 cells, but not in the presence of the glutamate transporter inhibitor PDC or in sodium-free media ($n = 3$) (**Fig. 3c**). Together, these results indicate that the hESC-differentiated immature astrocytes possessed functional glutamate receptors and transporters.

Propagation of calcium waves across astrocytes, activated by various stimuli, is important in glial and neuron-glial communication[35], and calcium wave dynamics are different in regionally distinct astrocytes[18,19]. Fluorescent intensity of Fluo-4 loaded hESC (line H9)-derived 6-month immature astrocytes was observed during mechanical stimulation of a small area <20 μm. In all cells tested, stimulation induced an intra- and intercellular calcium wave in the vicinity, which traveled outward to adjacent cells (**Fig. 3d** and **Supplementary Movie 1**). Wave propagation was found to be dependent upon extracellular ATP signaling, because it was reduced by the presence of apyrase, an ATP hydrolytic enzyme, but not of the gap junction blocker carbenoxolone (**Supplementary Fig. 4**). The distance traveled by the calcium waves was different between retinoic acid– and FGF8-specified astroglia (**Fig. 3d**). Application of the InsP3 receptor blocker 2-APB[36] reduced the calcium wave distance for both retinoic acid– and FGF8-astroglial groups (**Fig. 3d**). Astroglia generated without FGF8 treatment, which also display anterior characteristics (**Supplementary Fig. 2b**), propagated waves in similar

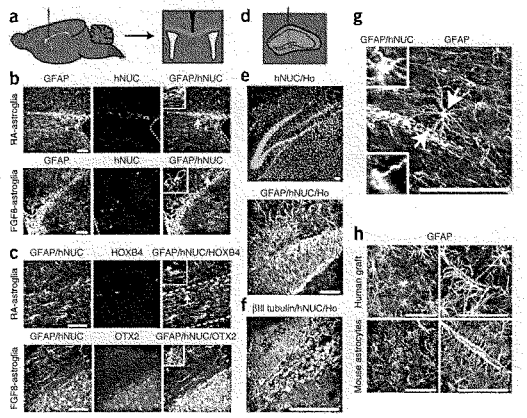

Figure 4 HPSC-derived astroglia retain their identity *in vivo*. (**a**) Illustration of intraventricular transplantation of hESC-derived astroglia and the resulting position of grafted cells. (**b**) One hundred days after transplantation, both retinoic acid–specified ($n = 3$) and FGF8-specified ($n = 4$) human cells (hNUC$^+$ = red) are present in ventricular areas (outlined with dashed lines), and express GFAP. Arrows indicate the human cells magnified in the insets. (**c**) Grafted, retinoic acid–specified human astrocytes (hNUC$^+$ = blue) in the corpus callosum (outlined with dashed lines) express HOXB4 (red, 65/65). In contrast, all of the FGF8-specified hNUC$^+$/GFAP$^+$ cells express OTX2 (red, 52/52). (**d**) Illustration of hippocampal transplantation. (**e**) Human astrocytes (red) survive and express GFAP but not βIII-tubulin (**f**) 6 weeks after transplantation to the adult hippocampus ($n = 4$ for each group). (**g**) Six months after transplantation of day 21 hESC-derived neural progenitors, human astrocytes (white arrow; hNUC$^+$/GFAP$^+$ shown in upper inset) extend processes onto endogenous blood vessels (outlined with dashes) with end feet (yellow arrow; shown in the lower inset on a single plane). (**h**) Mouse and human astrocytes exhibit distinct phenotypes, including process length and blood vessel association. Scale bars, 50 μm.

distances as that of the FGF8-specified astroglia (30 s; 106.5 ± 2.3 μm, $P = 0.1369$) and significantly different from that of retinoic acid–specified astroglia ($P < 0.001$) (data not shown). Thus, similar to astrocytes *in vivo*, hESC-derived immature astrocytes are competent for network communication.

Another function of astrocytes, especially immature astrocytes, is promotion of synaptogenesis[5,6,37]. To determine whether hPSC-derived immature astrocytes possess the same function, we cultured hESC-derived (day 21) neuronal progenitors alone, or in direct contact with immature astrocytes. The density of synapsin 1$^+$ puncta along the neurites was significantly ($P = 0.0119$) increased in neurons after 3 weeks of direct co-culture on hESC-derived (anterior) immature astrocytes compared to those without (**Fig. 3e**), suggesting the ability of hPSC-astrocytes to modulate synaptogenesis.

Regional and astroglial identity is retained *in vivo*

To determine whether hPSC-differentiated astroglia maintain their identity *in vivo*, we transplanted dissociated immature astrocytes, treated for 1 week with CNTF after 6 months of differentiation from line H9, into the lateral ventricles of neonatal mice (**Fig. 4a**). Thirty ($n = 2$ for retinoic acid group, $n = 2$ for FGF8 group) and 100 d ($n = 3$ for retinoic acid group, $n = 4$ for FGF8 group) after transplantation, grafted human cells, identified by human nuclear protein (hNUC), were observed as clusters adjacent to the lateral ventricles and as a stream of migrating cells in the corpus callosum. In every brain section examined, all of the transplanted hNUC$^+$ cells expressed a high level of GFAP (**Fig. 4b,c**). Cells that entered the corpus callosum were elongated in parallel with axons. Astroglial progenitor clusters (after 6 months without CNTF treatment, H9 line) transplanted directly into the adult mouse hippocampus also survived after engraftment (2 weeks; $n = 4$ for retinoic acid group and $n = 2$ for FGF8 group; 6 weeks; $n = 4$ for both groups) and continued to express GFAP (**Fig. 4d,e**), but not the neuronal marker βIII-tubulin$^+$, even in the neurogenic dentate gyrus (**Fig. 4f**). This result indicated that the hESC-derived astroglial progenitors or immature astrocytes retained their identity *in vivo*.

Immunostaining of the ventricle-transplanted cells for homeodomain transcription factors showed that all hNUC$^+$ cells in clusters and those migrating through the corpus callosum were positive for HOXB4 (day 30 = 70/70, day 100 = 65/65), but not for OTX2, and no hNUC-/GFAP$^+$ endogenous astrocytes in this region co-labeled with HOXB4 for the retinoic acid–specified astroglial group (**Fig. 4c**). In the brains transplanted with FGF8-specified immature astrocytes, all hNUC$^+$ cells were positive for OTX2 (day 100 = 52/52), but not HOXB4, and endogenous OTX2$^+$ astrocytes could be observed (**Fig. 4c**). Therefore, the regional specificity of astrocytes, which is acquired during early *in vitro* differentiation, is retained and not altered by the ectopic *in vivo* brain environment.

To determine whether *in vitro*–generated human astroglia can mature and integrate into the mouse brain, we examined whether they were in close apposition to blood vessels, a sign of contribution or signaling of astrocytes to the blood-brain barrier[38]. As blood-brain barrier formation requires coordinated development of blood vessels and astrocytes, we transplanted hESC-derived neural progenitors (day 21) to the ventricles of neonatal mouse brain and looked for direct connections of human GFAP$^+$ fibers to vessels. Few GFAP$^+$ cells were generated from grafted hESC-derived neuroepithelial cells within 3 months, as previously described[39]. However, 6 months after transplantation, a number of GFAP$^+$/hNUC$^+$ cells projected elongated fibers to blood vessels, with end feet directly contacting the vessels (**Fig. 4g,h** and **Supplementary Movie 2**). In contrast, endogenous mouse astrocytes are smaller, and the somas directly surround vessels. This distinction is similar to phenomena observed in adult human and rodent tissues[40]. These results indicate that the hPSC-derived astroglia can mature and participate in blood-brain barrier structure formation and that they exhibit some unique features of human astrocytes even in the mouse brain.

DISCUSSION

We have developed a chemically defined system for efficiently directing hPSC-derived neural progenitors to a nearly uniform population of astroglial progenitors and immature astrocytes through

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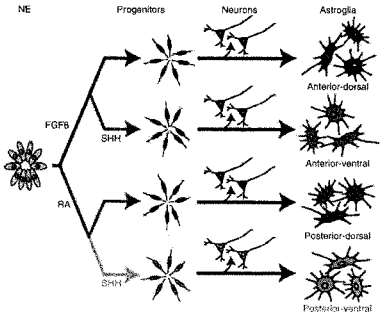

Figure 5 Hypothesis of astroglial subtype specification. The regional identity (anterior-posterior, dorsal-ventral) of astrocytes is determined when early neuroepithelial cells (NE, neural stem cells) are patterned to regional progenitors by morphogens such as retinoic acid and SHH. The regionalized progenitors first give rise to subclasses of neurons and then, during gliogenesis, generate regional-specific astrocytes with functionally distinct characteristics.

long-term expansion of dissociated progenitors in the presence of FGF2 and EGF. The *in vitro*–produced human immature astrocytes possess functional hallmarks of primary astrocytes, including responses to glutamate, propagation of calcium waves, promotion of synaptogenesis and participation in blood-brain barrier formation. Notably, we provide evidence that regionally and functionally diversified astroglial subtypes can be efficiently specified through patterning of early neuroepithelial cells with the same set of morphogens used for generating neuronal subtypes. Both astroglial identity and regional characteristics are maintained after long-term *in vitro* expansion and after transplantation into the mouse brain. Such human immature astrocytes, which can be generated in large quantities from an almost unlimited source of stem cells, should be useful in basic research, drug discovery and regenerative biology.

The regional and functional heterogeneity of astroglia has been well recognized[41]. However, it remains unclear whether this heterogeneity arises from intrinsic developmental programs or exclusively from adaptation to environmental cues. We have shown here that the regional identity of neuroepithelial cells, specified by a single morphogen, is maintained during subsequent differentiation. Comparisons of astroglial subtypes revealed differential onset of S100β and GFAP expression, cellular proliferation, gene expression and calcium wave propagation. Thus, the regional identity of astroglial cells is at least partially determined during neuroepithelial patterning, as has been previously postulated[22,42,43], and we propose that combinatorial morphogen patterning of neuroepithelial cells may lead to the generation of increasingly diversified astroglial subtypes (Fig. 5). This hypothesis suggests that regionalized neural progenitors migrate to target brain regions and then give rise to neurons before becoming astroglial cells, which may explain why we do not observe clear differential migration patterns of regionalized astroglia. Nevertheless, astroglial progenitors and immature astrocytes tend to target the white matter.

Functional properties of astroglia, particularly those of regional astroglia, are generally considered the outcome of responses to local brain environments[44]. Given the minimal presence of neurons and absence of immune cells in our culture system, our data suggest that at least some functions, described here, are intrinsic when astroglia are born. It should be pointed out that the astroglial cells in our culture system correspond to those at an early stage of the developing human brain. In the developed brain, astrocytes may well acquire additional mature functions, especially in response to local cues[45]. Furthermore, both the astroglial identity and regional characteristics are maintained after long-term *in vitro* expansion of their progenitors and after transplantation into the mouse brain environment. The intimate connections of hPSC-derived astrocytes with blood vessels suggest functional ability *in vivo*, though further work is needed to determine whether these cells can affect brain signaling or behavior.

Astrocytes in the human nervous system appear more complex than those in lower mammals[40]. Our present findings indicate that differentiation of human ESCs to a robust population of GFAP$^+$ astroglia (which takes at least 12 weeks) is substantially slower than that of mouse ESCs (which takes ~2 weeks), corresponding to astroglial development in the human brain. This prolonged development explains why hPSC-derived astroglial cells *in vitro* exhibit characteristics of immature rodent astrocytes *in vivo*, including the presence of voltage-gated currents[34] and induction of neuronal maturation[37]. Nevertheless, the immature astrocytes appear to mature over time when co-cultured with neurons or transplanted into the brain to participate in blood-brain barrier formation. Our ability to derive and expand an enriched population of astroglial progenitors, as well as to differentiate them to immature astrocytes, will facilitate studies of the role of human astrocytes in the normal and diseased brain and of transplantation therapies for neurological diseases such as amyotrophic lateral sclerosis, as suggested previously with mouse primary astrocytes[46]. In addition, astroglial cells derived from patient-specific iPSCs offer yet another approach for therapeutic discovery.

METHODS

Methods and any associated references are available in the online version of the paper at http://www.nature.com/naturebiotechnology/.

Note: Supplementary information is available on the Nature Biotechnology website.

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AUTHOR CONTRIBUTIONS

R.K. and S.-C.Z. designed the experiments and wrote the manuscript. R.K., J.P.W., Y.L. and Z.-J.Z. performed the experiments. R.K., J.P.W., Y.L., Z.-J.Z. and S.-C.Z. analyzed the data.

COMPETING FINANCIAL INTERESTS

The authors declare no competing financial interests.

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ONLINE METHODS

HPSC culture. HESCs (line H9, passages 20-30; H7, passages 35-40) and iPSCs ((IMR90)-4)[47] were cultured as previously described[32]. Briefly, cells were passaged weekly by dispase (1 mg/ml, Gibco) treatment and by plating on a layer of irradiated mouse embryonic fibroblasts. The hPSC medium consisted of DMEM/F12, 20% Knockout serum replacement, 0.1 mM β-mercaptoethanol, 1 mM L-glutamine, nonessential amino acids (Gibco) and 4 ng/ml FGF-2 (R&D Systems).

Differentiation of HPSCs. HPSCs were first differentiated to neuroepithelia for 10 d, as detailed elsewhere[48]. From days 10-21, cells were treated with either 0.5 μM of retinoic acid (Sigma), 50 ng/ml of FGF8 (Peprotech), or 500 ng/ml of sonic hedgehog (SHH, R&D Systems). Neural progenitors in a form of rosettes were blown off by a pipette at day 15 and expanded in a suspension culture containing EGF (Sigma) and FGF2 (R&D Systems, 10 ng/ml) starting from day 21. The neural progenitor spheres were disaggregated into small clusters with a Pasteur pipette to reduce cell contact, thus promoting gliogenesis instead of neurogenesis[49]. For astroglial differentiation, progenitor spheres were dissociated with accutase (Chemicon) to single cells, attached with a laminin substrate in the presence of CNTF (10 ng/ml, R&D System), LIF (10 ng/ml, Millipore), or FBS (FBS, 10%, Gibco). Cells were additionally passaged to coverslips for immonocytochemistry.

Immunochemistry and western blot. For immunocytochemistry, fixed cells were stained as previously described[32]. For quantification of each sample (n), 10 optic fields were chosen randomly under the fluorescent filter for nuclear staining throughout the coverslips in areas which contained a similar density of Hoechst$^+$ cells and the total cells were counted with Metamorph software. The fluorescent filters were shifted during imaging to count the cells labeled by different antibodies in the same field in the same manner. The quantitative data were repeated twice or more in different cultures or those from different cell lines. For western blotting, 30 μg of cell lysates were resolved with SDS-PAGE and transferred to nitrocellulose membranes. Detection was performed with horseradish peroxidase-conjugated secondary antibodies and the ECL system (Thermo Scientific). Primary antibodies are listed in **Supplementary Table 1**.

Proliferation assay. Cells were attached on coverslips for 48 h and treated with 0.2 μM 5-Bromo-2′-deoxyuridine (BrdU) for 10 h. Cells were fixed with methauol for 10 min, followed by incubation with 2 N HCL for 20 min. Cells were immunostained with the BrdU antibody as described above.

Quantitative reverse transcription polymerase chain reaction (qRT-PCR). cDNA was prepared using Superscript III First-Strand Synthesis System (Invitrogen). qRT-PCR was performed with Power SYBR Green PCR Master Mix (Applied Biosciences) on a StepOnePlus System with standard parameters and values were normalized to glyceraldehyde 3-phosphate dehydrogenase (GAPDH), $n = 3$ for each. The primer sets used are listed in **Supplementary Table 2**.

Primary culture. Primary astrocyte cultures were prepared from E13.5 timed pregnant CF-1 mice (Charles River). Brain regions were surgically dissected based on anatomical markers, dissociated with trypsin (Invitrogen), and cultured in DMEM + 10% FBS until experimentation. All experiments were performed with cells during passages 2–5.

Electrophysiology. Whole-cell patch clamp recordings were performed and analyzed as previously described[6]. During the procedure, cells were bathed in a modified Hank's Buffered Saline Solution (HBSS) that contained (in mM): 140 NaCl, 3 KCl, 2 $CaCl_2$, 1 $MgCl_2$, 15 HEPES and 23 glucose (pH 7.4, 300 mOsm). The following chemicals were applied through a gravity-fed drug barrel system: 4-aminopyridine (4-AP, 1mM), L-glutamate (100 μM), alpha-amino-3-hydroxyl-5-methyl-4-isoxazole-propionate (AMPA) (100 μM), (2R)-amino-5-phosphonopentanoate/6-cyano-7-nitroquinoxaline-2,3-dione (AP5/CNQX) (20 μM), D,L-aspartate (100 μM), dihydrokainic acid (DHK, 100 μM), and L-serine-*O*-sulfate (SOS, 100 μM), all obtained from Sigma. For co-culture experiments, immature astrocytes were infected with lentiviral particles to express transgenic mCherry protein driven by the cytomegalovirus promoter, and co-cultured without or with day 28 hESC-derived neurons in neural media as previously described[6].

Glutamate clearance assay. The method for measuring the decrease of glutamate over time[50] was modified. using the Glutamine/Glutamate Determination Kit (Sigma). Anterior astroglia were differentiated for 7 months, plated at a concentration of 20,000 cells per well in a 48-well plate, and cultured for an additional 7 d in the presence of CNTF. Before the assay, cultures were equilibrated in HBSS buffer for 10 min. 50 μM L-glutamate solutions were prepared with either HBSS ± L-*trans*-pyrrolidine-2,4-dicarboxylic acid (PDC, 1mM, Sigma) or Na^+ free HBSS (modified by replacing equimolar KCL with NaCl) and incubated with the cells. After various time periods, the glutamate concentration remaining in the media was measured at 340 nm following the enzymatic reaction. HEK293 cells, which do not significantly uptake glutamate compared to primary astrocytes, were used as controls. After subtraction of the blanks (0 glutamate added), the decrease in the media, or uptake of glutamate by cells, was reported as μM of glutamate per μg of protein after being normalized to the total protein in each well. The protein content was determined by a BCA protein assay (Pierce).

Calcium wave imaging. Astroglial cells were incubated at 25 °C with HBSS and 1 μl each of Fluor-4 (4 μM, Invitrogen) and Pluronic F-127 (0.01%, Invitrogen) for 30 min. Cells were washed with HBSS and imaged with an immersion objective on a confocal microscope (described below). Calcium wave induction was done by mechanical stimulation with a flame polished pulled glass pipette controlled manually with a micromanipulator (WPI). Five random fields were chosen under microscopy and averaged for each n. Fluorescent images were taken every 2 s with or without 2-aminoethoxydiphenyl borate (2-APB, Tocris, 100 μM), carbenoxolone (Sigma, 100 μM) or apyrase (Sigma, 50 units/ml). Calcium wave distances were quantified using Metamorph software. Post-fixation nuclear counting confirmed similar plating densities of astrocytes (retinoic acid = 121.3 ± 7.2, FGF8 = 125.7 ± 26.7 per 428 μm^2, $P = 0.88$).

Astrocyte-neuronal co-cultures for synaptogenesis studies. Human ESC-derived neural progenitors (day 21) were cultured in the neuronal differentiation media alone or directly on a layer of hESC-derived immature astrocytes (10,000 cells/cm^2) for 3 weeks, similar as previously described[6]. The cultures were then fixed with 4% paraformaldehyde and immunostained for βIII-tubulin and synapsin 1. Neurons with elongated neurites were chosen by visualization of βIII-tubulin under confocal microscopy. Fluorescent filters were then switched for Synapsin 1 imaging, and the synapsin 1+ puncta along the βIII-tubulin+ neurites were counted with ImageJ software. The results were expressed as the number of puncta per unit neurite length.

Transplantation. Transplantation studies were conducted following protocols approved by the Animal Care and Use Committees at the University of Wisconsin-Madison. Cells were prepared for transplantation in artificial cerebral spinal fluid (Harvard Apparatus) at a concentration of 50,000 cells/μl. For ventricle transplants, 2 μl of the cell suspension was injected 1 mm from the midline between the Bregma and Lambda and 1 mm deep into the anterior lateral ventricles of both hemispheres of severe combined immunodeficiency (SCID)-beige (Taconic) P1 mice. For transplantation into the adult SCID mouse hippocampus, 2 μl of cells were injected with the sterotaxic coordinates of −2.46 mm for anterior-posterior, ± 2 mm for lateral, and −2.25 mm for dorsal-ventral. At various time periods after transplantation, animals were anesthetized, perfused with 4% paraformaldehyde, and processed for immunohistochemistry with antibodies listed in **Supplementary Table 2**. Sections were imaged with a confocal microscope (Nikon, D-Eclipse C1), and EZ-C1 software (version 3.5).

Statistical analysis. Results were expressed as mean ± s.e.m. For quantification, each dataset (n) was generated from a separate passage of hPSCs. $n = 3$ unless noted differently. Fields were randomly selected and P values were calculated by unpaired t-test. *, $P \leq 0.05$.

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RESEARCH Open Access

Astrocytes generated from patient induced pluripotent stem cells recapitulate features of Huntington's disease patient cells

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Abstract

Background: Huntington's Disease (HD) is a devastating neurodegenerative disorder that clinically manifests as motor dysfunction, cognitive impairment and psychiatric symptoms. There is currently no cure for this progressive and fatal disorder. The causative mutation of this hereditary disease is a trinucleotide repeat expansion (CAG) in the Huntingtin gene that results in an expanded polyglutamine tract. Multiple mechanisms have been proposed to explain the preferential striatal and cortical degeneration that occurs with HD, including non-cell-autonomous contribution from astrocytes. Although numerous cell culture and animal models exist, there is a great need for experimental systems that can more accurately replicate the human disease. Human induced pluripotent stem cells (iPSCs) are a remarkable new tool to study neurological disorders because this cell type can be derived from patients as a renewable, genetically tractable source for unlimited cells that are difficult to acquire, such as neurons and astrocytes. The development of experimental systems based on iPSC technology could aid in the identification of molecular lesions and therapeutic treatments.

Results: We derived iPSCs from a father with adult onset HD and 50 CAG repeats (F-HD-iPSC) and his daughter with juvenile HD and 109 CAG repeats (D-HD-iPSC). These disease-specific iPSC lines were characterized by standard assays to assess the quality of iPSC lines and to demonstrate their pluripotency. HD-iPSCs were capable of producing phenotypically normal, functional neurons *in vitro* and were able to survive and differentiate into neurons in the adult mouse brain *in vivo* after transplantation. Surprisingly, when HD-iPSCs were directed to differentiate into an astrocytic lineage, we observed the presence of cytoplasmic, electron clear vacuoles in astrocytes from both F-HD-iPSCs and D-HD-iPSCs, which were significantly more pronounced in D-HD-astrocytes. Remarkably, the vacuolation in diseased astrocytes was observed under basal culture conditions without additional stressors and increased over time. Importantly, similar vacuolation phenotype has also been observed in peripheral blood lymphocytes from individuals with HD. Together, these data suggest that vacuolation may be a phenotype associated with HD.

Conclusions: We have generated a unique *in vitro* system to study HD pathogenesis using patient-specific iPSCs. The astrocytes derived from patient-specific iPSCs exhibit a vacuolation phenotype, a phenomenon previously documented in primary lymphocytes from HD patients. Our studies pave the way for future mechanistic investigations using human iPSCs to model HD and for high-throughput therapeutic screens.

Keywords: Huntington's disease, Induced pluripotent stem cells, Neural differentiation, Astrocytes, Disease modeling

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Background

Huntington's disease (HD) is a fatal, progressive, neurodegenerative disorder that affects approximately 1 in 10,000 people [1]. The disease clinically manifests as motor dysfunction, typified by involuntary movements, cognitive abnormalities and psychiatric disturbances [2]. The genetic defect for this autosomal dominant disorder is a trinucleotide repeat expansion (CAG) in exon 1 of *huntingtin* (*HTT*), which results in an expanded polyglutamine tract at the N-terminal of the HTT protein [3]. Proteolytic cleaving of the abnormal HTT protein results in insoluble aggregates that form characteristic inclusions within the nucleus and cytoplasm of affected cells [4,5]. Although the wild-type HTT protein is ubiquitously expressed [6], there is a preferential accumulation of the mutant HTT protein in neurons, including medium spiny neurons of the striatum [7]. Mutant HTT aggregates have also been detected in other neural cell types such as astrocytes in the brain of HD patients [8,9]. Regional neurodegeneration characterized by striatal degeneration and cortical loss is a hallmark of HD pathology [10,11]. Other areas of the brain, such as the hippocampus, are also affected [12].

HD manifests in both a juvenile form that has a childhood onset, and a more common form that presents at the middle age. Unaffected individuals have up to 35 CAG repeats within the *HTT* gene and HD is associated with repeats of 36 or more [13]. There is an inverse correlation with CAG repeat length and onset of disease, with longer repeats (>55 CAG) associate more commonly with a juvenile onset [14]. Paternal inheritance of the *HTT* mutation may result in CAG repeat length instability and an increase in CAG repeat length [15,16]. Although HD is a defined genetic disorder and the causative mutation was identified almost two decades ago [3], the exact mechanism by which mutant *HTT* results in neuronal degeneration has yet to be determined, and major therapeutic advances have been lacking. Various *in vitro* cell culture systems [17,18] and animal models [19,20] have been developed to investigate HD pathogenesis and have provided numerous theories, such as abnormal mitochondrial bioenergetics, oxidative damage, transcriptional dysregulation and abnormal vesicle trafficking [2,5,21]. The potential role of glia cells, such as astrocytes, in the pathogenesis of HD is also being investigated [9,22-24]. For example, expression of HTT with expanded polyglutamine in astrocytes has been shown to affect glutamate transport and exacerbate neurological phenotypes in a mouse model of HD [22,23]. The cholesterol defect is also observed in astrocytes in multiple rodent models of HD [25]. A direct pathogenic role of astrocytes in the disease process of patients remains unknown.

The discovery of a combination of transcription factors that could reprogram somatic cells into cells exhibiting pluripotency has provided researchers with a revolutionary tool to study human biology and diseases [26,27]. The induced pluripotent stem cells (iPSCs) can be derived from many somatic cell types, including easily accessible dermal fibroblasts and peripheral blood lymphocytes [28,29]. Similar to human embryonic stem cells (hESCs), iPSCs can self-renew and expand indefinitely in culture [27,30]. More importantly, they share the capacity to generate any cell types in the body, a property that is particularly useful for the study of neurological diseases [31-35]. The pluripotency of iPSCs enables the production of neurons and glia from healthy individuals and from patients with diseases. This remarkable feature of iPSCs facilitates the study of brain cell types that are difficult to obtain from living individuals. Here we report the generation of iPSCs from a male patient with an adult form of HD (F-HD-iPSCs) and from his daughter with juvenile onset HD (D-HD-iPSCs). Consistent with previous reports, functional neurons can be derived from both HD-iPSCs that are phenotypically normal. However, when astrocytes were differentiated from these iPSCs, we identified a cellular vacuolation phenotype that has not been reported in neural cells, but observed in patient lymphocytes with HD. The ability of the HD-iPCSs to replicate a disease relevant phenotype that is found in primary patient tissues supports the use of patient-specific iPSCs for disease modeling and opens doors for future high-throughput screens.

Results

Derivation and characterization of HD-iPSC lines

To derive the iPSC lines, we retrovirally introduced the four reprogramming factors (Oct3/4, Sox2, c-MYC and Klf4) [26,27] into dermal fibroblasts harvested from a male patient with adult onset HD (50 CAG repeats), his daughter with juvenile-HD (109 CAG repeats) and non-related neonatal foreskin fibroblasts (28 CAG repeats) as controls. Colonies generated from all three fibroblast cell lines exhibited typical iPSC morphology (Figure 1A), similar to conventional hESC lines and maintained a normal karyotype after continuous expansion (Figure 1B). All cell lines highly expressed alkaline phosphatase (Figure 1C) and hESC makers Nanog, OCT3/4, SSEA4 and TRA 1-60 (Additional file 1: Figure S1A). *In vitro* assessment of pluripotency was performed using an embryoid body assay whereby the iPSCs were cultured in suspension under conditions that favored spontaneous differentiation. The cell lines examined were capable of differentiating into cells of mesodermal, endodermal and ectodermal origin (Additional file 1: Figure S1B), confirming *in vitro* pluripotency. To further evaluate the pluripotency of the iPSC lines, we utilized a functional *in vivo* teratoma formation assay. All of the iPSC lines exhibited the capacity to form

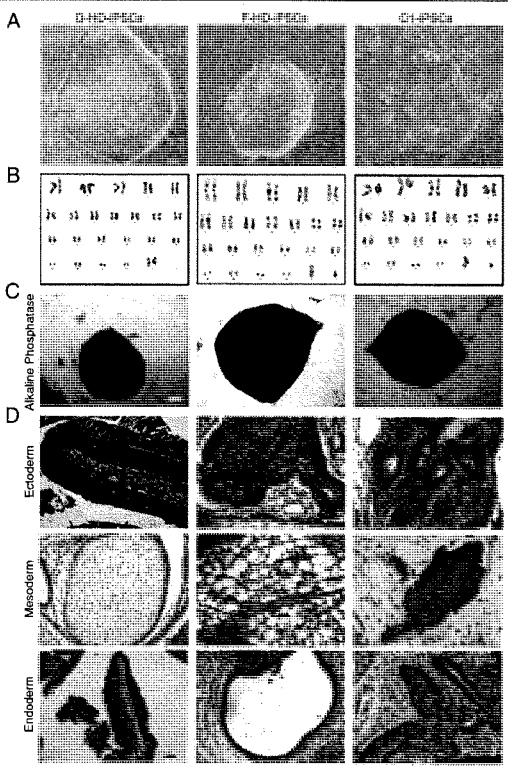

Figure 1 Characterization of induced pluripotent stem cell lines (iPSCs). A, B: iPSC lines generated from fibroblasts exhibited typical ESC morphology by phase contrast microscopy (**A**) and maintained a normal karyotype (**B**). **C**: iPSCs strongly expressed the pluripotency marker alkaline phosphatase, whereas the surrounding MEFs were negative. **D**: Hematoxylin and eosin staining of teratomas derived from iPSC lines confirmed pluripotency by the presence of tissues representing the three major germ layers: ectoderm, endoderm, mesoderm. Scale bars: 100 μm.

tumors in immunocompromised mice that were consistent with teratomas. Tissues representative of the three major germ layers were detected in each tumor (Figure 1D). In addition, we also confirmed the expression of both wild-type and mutant HTT protein in the HD-daughter fibroblasts and derived iPSCs with Western blot analysis (Additional file 1: Figure S1C).

HD iPSC-derived neural progenitors form functional neurons *in vitro*

To assess the neurodevelopmental potential of the HD-iPSC lines, we employed two approaches to differentiate iPSCs into neurons: a feeder-free method using an iPSC-aggregate intermediate to form neural progenitors [36] and a co-culture protocol that uses a mouse stromal cell line to induce neural differentiation [37]. For the feeder-free method, iPSC colonies were grown in suspension in the presence of neural induction medium to generate neurospheres that could be maintained and further passaged (Figure 2A). When plated on poly-l-ornithine-laminin (PLO) coated plates, neurospheres attached and formed neural rosettes expressing neural progenitor marker nestin (Figure 2B). The neural rosettes gave rise to neurons that expressed the neuronal marker beta III

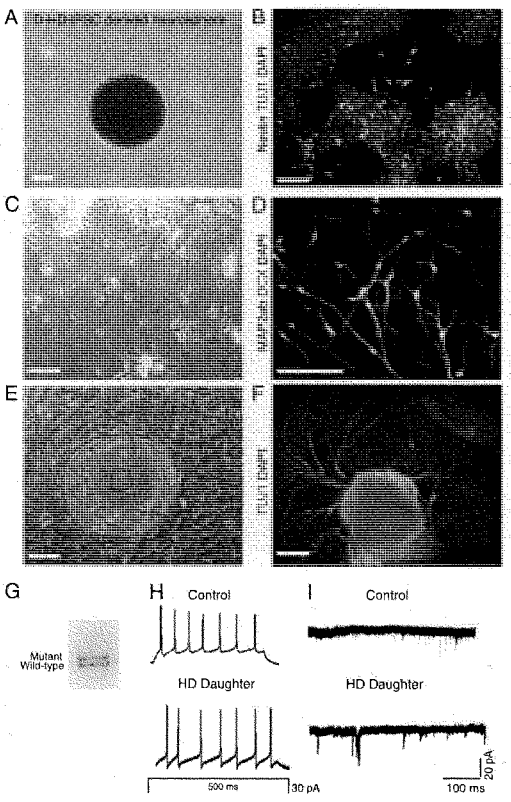

Figure 2 Differentiation of D-HD-iPSCs into neural progenitors, immature and mature functional neurons. A: A sample image of a neurosphere generated from the D-HD-iPSC line using the feeder-free differentiation protocol. **B**: Nestin-positive neural progenitors displaying rosette formation and immature (TUJ1$^+$) neurons. **C**: Phase contrast image of neurons derived from D-HD-iPSCs. **D**: Mature (MAP2ab$^+$) and doublecortin (DCX$^+$) expressing neurons. **E**: Neural progenitor derived from D-HD-iPSCs using the PA6 cell line. Stromal cell monolayer observed in the background. **F**: Large networks of TUJ1$^+$ neurons emanating from neural progenitors using the PA6 stromal cell line for induction. Scale bars: 100 μm. **G**: D-HD-iPSC derived neurons express both mutant and wild type HTT proteins by Western blot analysis. **H**: Action potentials recorded from neurons derived from D-HD-iPSCs and from C1-iPSCs. **I**: Miniature excitatory post-synaptic currents (mEPSCs) recorded from iPSC-derived neurons.

tubulin (TUJ1; Figure 2B). For terminal differentiation, the neural progenitors cells were dissociated into single cell suspension and plated on PLO coated plates or coverslips in the presence of neural differentiation medium. Differentiated cells exhibited a typical neuronal morphology (Figure 2C) and expressed neuronal markers microtubule associated protein 2ab (MAP2ab) and/or doublecortin (DCX; Figure 2D). No significant morphological differences were observed for neurons generated from either F-HD-iPSCs or D-HD-iPSCs under the

culture conditions, compared to neurons derived from control C1-iPSCs.

For the co-culture method of neural differentiation, iPSCs were mechanically dissociated into small colonies and seeded onto the mouse stromal cell line PA6, which has been shown to induce neural differentiation of hESCs [37,38]. Within one week of culture on PA6, iPSCs differentiated into colonies with characteristic neural progenitor morphology (Figure 2E). After three weeks of co-culture, many cells exhibited neuronal morphology and expressed TUJ1 (Figure 2F). Both HD- and C1-iPSCs were capable of differentiating into neurons via co-culture with the PA6 stromal cell line. Furthermore, both wild-type and mutant HTT proteins were expressed in neural progenitors and neurons derived from the D-HD-iPSCs by Western blot analysis (Additional file 1: Figure S1C and Figure 2G).

To assess physiological properties of neurons derived from the HD-iPSCs, we performed electrophysiological analysis. Neural progenitor cells derived from each cell line were dissociated into single-cell suspension and plated on a monolayer of rat hippocampal astrocytes for three weeks [39]. Whole-cell patch-clamp recordings showed that neurons from HD-iPSCs exhibited evoked action potentials; similar to those elicited by C1-iPSCs-derived neurons (Figure 2H). Miniature excitatory post-synaptic currents were also detected for HD-iPSC-derived neurons, providing evidence of functional synaptic transmission (Figure 2I). We did not detect overt neuronal functional defects or alterations under the same experimental conditions from either HD-iPSCs.

HD-iPSC-derived neural progenitors engraft, survive and generate neurons *in vivo*

We next investigated the short-term *in vivo* engraftment potential of HD-iPSC-derived neural progenitor cells by transplanting them into the adult mouse brain. To allow for identification of transplanted cells, we expressed green fluorescent protein (GFP) in F-HD-iPSCs and differentiated them into neural progenitors via the feeder-free method (Figure 3A). Neural progenitor cells were stereotaxically injected into the dorsolateral area of subventricular zone (SVZ) of the lateral ventricles of adult immunecompromised mice (Figure 3B). Adult SVZ provides a neurogenic microenvironment and newly generated neurons from endogenous neural progenitors at SVZ migrate towards the olfactory bulb along a route termed the rostral migratory stream (RMS) [40]. At six to eight week post-transplantation, GFP^+ cells were found in the RMS (Figure 3C) and the olfactory bulb (Figure 3D) and were positive for human nuclei antibody (HNA), confirming that GFP^+ cells were originated from transplanted human neural progenitor cells. In addition, some GFP^+ cells were positive for the neuron-specific nuclear marker NeuN in the olfactory bulb and exhibited morphology typical of mature granule cells (Figure 3E). Thus, neural progenitors derived from HD-iPSCs survive and are capable of differentiating into neurons within the adult mouse brain *in vivo*.

Astrocytes derived from HD-iPSCs exhibit increased cytoplasmic vacuolation

Astrocytes have been shown to exhibit non-cell-autonomous effects on neurons when expressing a HTT protein with a polyglutamine expansion [22,23]. To examine the driect effect of mutant HTT on astrocytes, we differentiated neural progenitors into astrocytes by culturing in the astrocyte medium (Figure 4A). Cells were continually passaged and maintained in the astrocyte medium until they exhibited typical astrocyte morphology. All three iPSC lines were capable of differentiating with similar efficiency into cells that expressed the astrocyte markers glial fibrillary acidic protein (GFAP) and S100β (Figure 4B).

In contrast to the absence of an obvious cellular phenotype of neurons with a *HTT* mutation, we detected a rapid accumulation of discrete clear vacuoles of variable number and size within the cytoplasm of astrocytes derived from D-HD-iPSCs (Figure 5A). Similar vacuoles were observed in lower numbers in astrocytes derived from the F-HD-iPSCs. However, vacuoles were rarely observed in C1-iPSC derived astrocytes (Figure 5A). Next, we quantified the percentage of astrocytes that contained cytoplasmic vacuoles. One day after plating, 24% of astrocytes derived from the D-HD-iPSCs already contained cytoplasmic vacuoles, compared to 2.7% of astrocytes derived from the F-HD-iPSCs and 1.1% of control astrocytes (600 cells per line; 4 different experiments). After seven days, the numbers of D-HD astrocytes with cytoplasmic vacuoles increased to 34%, compared to 2.7% of HD-father astrocytes and 1.1% of astrocytes derived from control iPSCs (Figure 5B; 600 cells per line; 4 different experiments).

The cytoplasmic vacuoles were negative for the intermediate filament protein GFAP and appeared empty (Figure 5C). To determine whether the cytoplasmic vacuoles were autophagosomes, we performed immunocytochemistry for the marker Light Chain 3 (LC3) that binds to autophagocytic membranes [41]. Under basal culture conditions, LC3 staining was weakly detected within the cytoplasm of astrocytes, but rarely colocalize with cytoplasmic vacuoles (Figure 5D). To enhance the detection of autophagosomes, we treated astrocytes overnight with chloroquine, a drug that accumulates in lysosomes and prevents fusion of lysosomes with autophagosome by altering lysosomal pH. Chloroquine treatment significantly increased the number of cytoplasmic vacuoles for all three cell lines examined, with D-HD

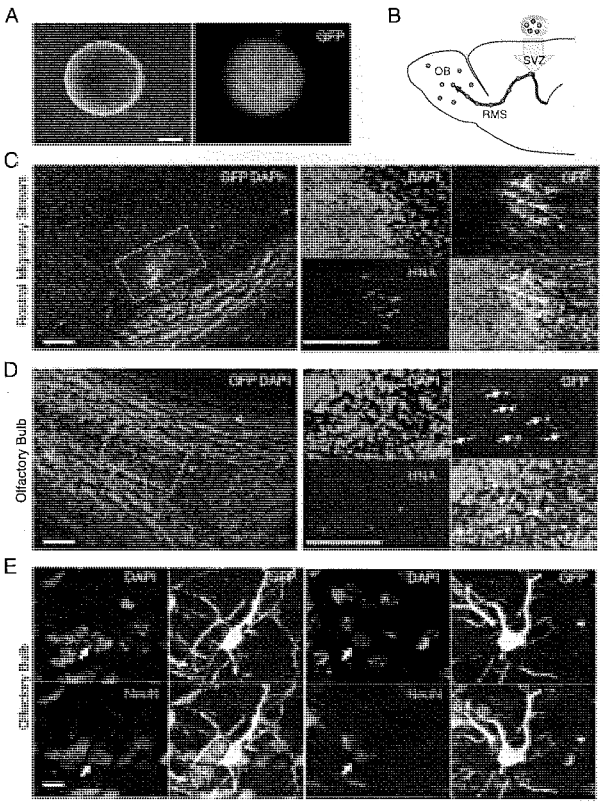

Figure 3 Transplantation and engraftment of neural progenitors derived from F-HD-iPSCs into the adult mouse brain. A: Neurospheres derived from F-HD-iPSCs expressing GFP prior to transplantation (phase contrast and fluorescence demonstrating GFP expression). **B**: A diagram illustrating neural progenitor cell transplantation. GFP-labeled neural progenitor cells were injected into the subventricular zone (SVZ) and migrated along the rostral migratory stream (RMS) to the olfactory bulb (OB). GFP and human nuclei antibody (HNA) positive neurons were detected in the RMS (**C**) at six weeks and in the OB (**D**) at eight weeks post-transplantation. **E**: NeuN$^+$ GFP expressing cells exhibiting granule cell morphology were detected in the OB eight weeks post-transplantation. Unless otherwise indicated, scale bars: 100 μm.

astrocytes exhibiting the most vacuolation (Figure 6A). The chloroquine-induced vacuoles were mostly autophagsomes that were positive for LC3. However, LC3 did not colocalize with all of the cytoplasmic vacuoles observed (Figure 6B), suggesting the existence of a different type of vacuoles that might associate with the *HTT* mutation in astrocytes.

To further characterize the cytoplasmic vacuolation observed in HD-astrocytes, we performed transmission electron microscopy (TEM). Ultrastructural examination of astrocytes confirmed the presence of numerous electron clear vacuoles with variable size and shape (Figure 7A). Autophagic vacuoles containing 1-2 myelin whorls were also detected within the cytoplasm of cells, but with much lower abundance (Figures 7B and 7C). Occasionally, we also observed astrocytes with clear empty vacuoles (Figure 7D), autophagosomes (Figure 7E) and dense granules that were compatible with lipid

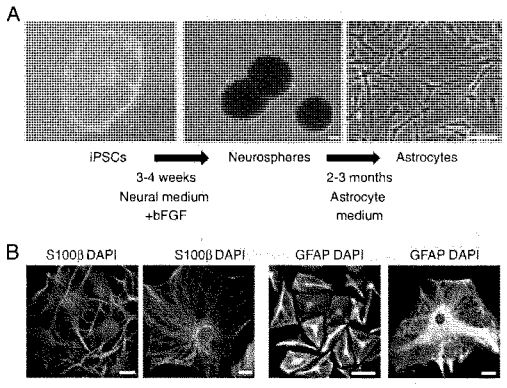

Figure 4 Generation of astrocytes from iPSCs. A: A multi-step protocol was used to generate astrocytes. iPSCs were initially differentiated into neurospheres using a feeder-free protocol and subsequently differentiated into astrocytes. **B**: Astrocytes generated from HD-iPSCs exhibited a typical astrocyte morphology and expressed astrocyte markers glial fibrillary acidic protein (GFAP) and S100β. Scale bars: 100 μm (A) or 20 μm (B).

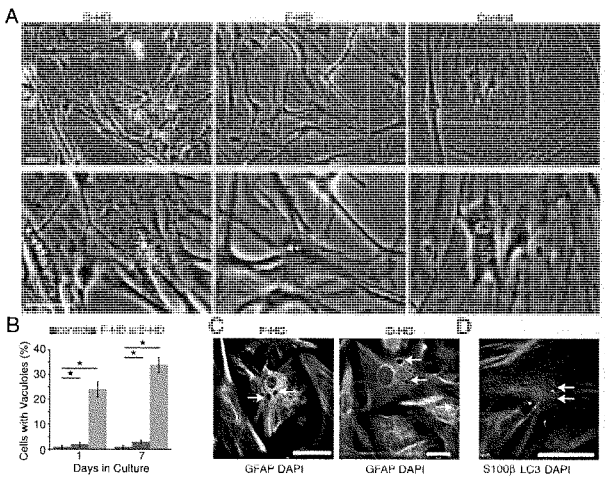

Figure 5 Astrocytes generated from the D-HD-iPSCs with increased cytoplasmic vacuolation. A: Vacuoles were detected in the cytoplasm of astrocytes (arrows) under phase contrast microscopy. The number of vacuoles varied depending on the iPSC line used to generate the astrocytes. **B**: Quantification of cytoplasmic vacuolation. Values represent mean ± SEM (n = 4; *: $P < 0.0001$; ANOVA). **C**: Cytoplasmic vacuoles appeared empty and were negative for GFAP staining. **D**: The autophagosomal marker LC3 was weakly detected in astrocytes grown under normal culture conditions and rarely colocalized with cytoplasmic vacuoles. Vacuoles often appeared empty (arrows). Scale bars: 50 μm.

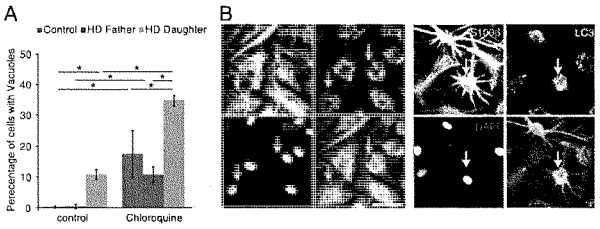

Figure 6 Enhanced vacuoles formation in astrocytes after chloroquine treatment. A: Overnight treatment of astrocytes with the autophagy inhibitor chloroquine resulted in increased cytoplasmic vacuolation for all cell lines examined, with D-HD-astrocytes exhibiting the largest number of vacuoles. **B**: S100β expressing astrocytes exhibited increased cytoplasmic staining with the autophagic vacuole marker LC3, after treatment with chloroquine. Scale bar: 50 μm.

droplets (Figure 7F) coexisting. Consistently, treatment with chloroquine increased the numbers of vacuoles detected within the cytoplasm of astrocytes and many had the appearance of lysosomes that were not electron clear (Figures 7G, 7H, and 7I). Together, these studies suggest that astrocytes with an *HTT* mutation exhibit a rapid accumulation of electron clear vacuoles in a CAG-dose-dependent manner.

Discussion

HD is a devastating neurological disorder for which there is currently no cure and few therapeutic options.

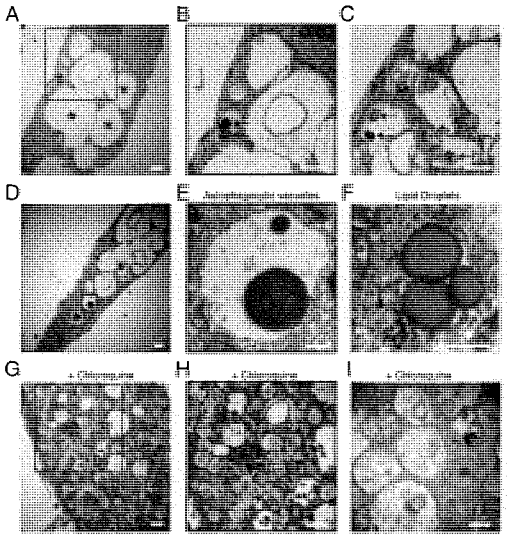

Figure 7 Ultrastructural changes in astrocytes derived from D-HD-iPSC. A: Numerous electron clear vacuoles were observed within the cytoplasm of astrocytes. **B, C**: A few autophagocytic vacuoles with myelin whorls (arrows) in astrocytes. **D**: Sample image of an astrocyte with many empty cytoplasmic vacuoles. Higher magnification revealed an autophagocytic vacuole with myelin whorls (**E**) and large spherical cytoplasmic granules representing lipid droplets (**F**). **G, H, I**: Chloroquine treated astrocytes exhibited numerous cytoplasmic vacuolation and proliferation of lysosomes. Scale bars: 2 μm (A-D, G, H) or 500 nm (E, F, I).

Given the severity of HD, there is a great need for model systems that can be used to further our understanding of the pathogenesis of this disease and as screening tools to discover or evaluate therapeutic compounds. In this study, we developed an *in vitro* model system derived from cells harvested from HD patients with unique genetic relationship between iPSC lines. One iPSC line was derived from a male carrying *an HTT* mutation with 50 CAG repeats and with adult onset HD. The second line was derived from his daughter with an *HTT* mutation of 109 CAG repeats and with juvenile onset HD. Trinucleotide repeat length frequently increases in the offspring of affected fathers, a phenomenon that is accentuated with longer paternal repeat lengths and that accounts for genetic anticipation [15,16]. The underlying mechanism for this genetic instability is not well understood. The HD-iPSCs of a father and child pairs, including cells from the father and the daughter reported here, could potentially be used as a model system to examine this intriguing phenomenon.

The HD-iPSC lines derived in this study exhibit typical hESC morphology, express pluripotency markers, maintain a normal karyotype and generate teratomas *in vivo* [42]. All lines were able to form neural progenitor cells, which in turn terminally differentiated *in vitro* into phenotypically normal, functional neurons that could fire action potentials and exhibit functional synaptic transmission. Although mutant HTT protein was present in HD-iPSC-derived neurons, an abnormal neuronal phenotype was not detected under basal conditions [43]. The lack of an obvious abnormality at the neuronal level under normal conditions has been previously reported by investigators utilizing HD-iPSCs [44]. Moreover, a general lack of neuronal phenotype has indicated in studies using iPSCs derived from patients with other neurodegenerative diseases, such as dopaminergic neurons for Parkinson's disease (PD) [45] and motor neurons for ALS [46]. These findings suggest that simply directing iPSCs to a specific neuronal subtype may not be sufficient to produce disease phenotype for certain aging-dependent neurological disorders and that extensive environmental manipulation or extended observation in culture may be required. For instance, cellular stressors leads to toxicity of HD iPSC-derived neurons under medium spiny neuron differentiation protocol [43]. The environmental cues needed to induce neurodegeneration in HD patients may be complex, requiring an intricate milieu of growth factors, morphogens and appropriate stressors. It may be necessary to further define the *in vitro* culture conditions to fully recapitulate the neuronal pathology observed in patients, such as the formation of HTT cellular inclusions.

The inability to maintain human neurons for long period of time has limited our ability to model late onset neurological diseases in culture; however, the development of patient specific iPSC technology has opened up the possibility of combining animal model systems with cell transplantation for longitudinal studies. We assessed the short-term *in vivo* engraftment capability of F-HD-iPSCs. We demonstrated that neural progenitors derived from F-HD-iPSCs transplanted into neurogenic SVZ of adult NOD-SCID mice were able to migrate along the RMS and generate neurons in the olfactory bulb. Importantly, the HD-iPSC derived cells were able to survive in the mouse brain for at least eight weeks post-transplantation. The results of our xenotransplantation experiments provide a foundation for future long-term engraftment studies and such a system could potentially be utilized to evaluate long term neuronal survival and degeneration *in vivo* and as a preclinical *in vivo* model for testing of therapeutic treatments.

Astrocytes are an abundant cell type in the adult brain and they perform essential and complex functions such as providing metabolic and trophic support for neurons, as well as overall structural support [47,48]. Astrocyte dysfunction has been implicated in the pathogenesis of several neurodegenerative diseases, including ALS [49,50], PD [51] and Alzheimer's disease [52]. The contribution of astrocytes to the development and progression of HD remains to be elucidated [9,22]. Recent studies have shown that expression of mutant N-terminal Huntingtin fragment in astrocytes suppresses BDNF secretion [53]. One of the advantages of using patient-derived iPSCs to develop an *in vitro* experimental system is the ability of the iPSC to generate any cell types of interest [31]. We utilized the pluripotent property of iPSCs and differentiated them into $GFAP^+$ and $S100\beta^+$ astrocytes. Strikingly, discrete, variably sized, clear vacuoles were detected within the cytoplasm of astrocytes derived from both HD-iPSCs, with D-HD-astrocytes had significantly higher number of cytoplasmic vacuoles. When examined by electron microscopy, the cytoplasm contained clear vacuoles that appeared empty, in addition to lower numbers of autophagic vacuoles and lipid droplets. Interestingly, cytoplasmic vacuolation has been observed in primary lymphoblasts harvested from individuals with HD and a correlation was found between the CAG repeat-length and the number of cytoplasmic vacuoles [54,55]. Consistent to what we observed in astrocytes, ultrastructural findings of the lymphoblasts were found to exhibit increased numbers of empty vesicles, autophagocytic vacuoles and lipid droplets.

Successful modeling of neurological disorders using iPSC technology have been reported, but mainly with neurodevelopmental disorders, such as spinal muscular atrophy [56], Rett syndrome [57] and familial dysautonomia [58]. Although many disease-specific iPSC lines for neurodegenerative diseases have been generated, few

published studies have identified a disease-related phenotype [31]. In our study, we identified a phenotype in astrocytes generated from iPSCs derived from patients with the neurodegenerative disorder HD. Notably, this phenotype was detected under basal conditions without additional stressors. Importantly, the characteristics of vacuoles in astrocytes was consistent with those seen in primary lymphoblasts harvested from HD patients [54,55], suggesting cellular vacuolation may be a disease associated abnormality that may be used as a biomarker for HD. Future studies will focus on further determining the disease-relevance and mechanistic studies to explore the relationship of the phenotype to HD pathogenesis.

Conclusion

We have derived patient specific iPSCs from a daughter and her father affected with HD, which provide a unique *in vitro* system to study HD, a defined, genetic, neurodegenerative disorder. The iPSCs from both diseased cell lines were differentiated into neural progenitor cells and further into functional neurons *in vitro*, and give rise to neurons in the adult mouse brain after transplantation *in vivo*. Astrocytes derived from HD iPSCs exhibit increased cytoplasmic vacuolation. Most importantly, we were able to recapitulate a phenotype under basal conditions that has previously been documented in primary cells harvested from HD patients. These results pave the way for future mechanistic studies of HD pathogenesis, disease modeling and for high-throughput therapeutic screens.

Methods

Induced pluripotent stem cell derivation and characterization

Skin biopsies were obtained from a male patient with adult onset Huntington's disease (50 CAG repeats) and his daughter with juvenile onset HD (109 CAG repeats). Dermal fibroblast cultures were established from skin biopsies for iPSC derivation as previously described [59]. Unrelated neonatal foreskin fibroblasts were acquired from American Type Culture Collection (CRL-2097, 28 CAG repeats) for generation of control iPSCs. iPSC lines were derived by retroviral transduction of the four factors (Oct3/4, Sox2, c-MYC and Klf4) according to previously published methods [60]. The iPSC lines were maintained on irradiated mouse embryonic fibroblasts (MEF) in hESC medium (hESM) consisting of Dulbecco's modified Eagle medium (DMEM)/F12 (Invitrogen) supplemented with 20% Knock-out serum replacement (KOSR, Invitrogen), 2 mM L-glutamine, 0.1 mM β-mercaptoethanol, 0.1 mM non-essential amino acids solution (NEAA), and 8 ng/ml of recombinant human basic fibroblast growth factor (bFGF, Preprotech). G-banding for karyotype analysis was performed for all iPSC lines by the Cytogenetics Core of the Johns Hopkins Medical Institution. All procedures followed approved protocol by Institutional IRB and ISCRO Committees.

Pluripotency marker expression was assessed with immunohistology as previously described [59,61]. Cells were fixed with 4% paraformaldehyde for ten minutes at room temperature, washed with phosphate buffered saline (PBS) and blocked with 10% donkey serum in 0.25% Triton X-100 in PBS for one hour. Specimens were incubated in a solution of 1% donkey serum in PBS overnight at 4°C with the following primary antibodies: goat anti-Nanog (R&D Systems, 1:250), mouse anti-TRA 1-60 (Millipore, 1:250), mouse anti-SSEA4 (Millipore, 1:400), mouse anti-OCT3/4 (Santa Cruz, 1:400). Following three washes with PBS, the samples were incubated with the appropriate secondary antibody in PBS with 1% donkey serum for one hour at RT. Samples were washed with PBS and counter-stained with 4',6-diamidino-2-phenylindole, dihydrochloride (DAPI) to visualize the nuclei. FITC- and Cy3-conjugated secondary antibodies were obtained from Jackson ImmunoResearch. Images were acquired with confocal microscopy system. Alkaline phosphatase activity was detected using SigmaFAST BCIP/NBT kit (Sigma) according to the manufacturer instructions.

For *in vitro* assessment of pluripotency, an embryoid body assay was performed as previously described [59]. iPSCs were enzymatically detached from MEF by incubation with collagenase IV (Invitrogen). The colonies were washed with PBS (Invitrogen), re-suspended and cultured in suspension using ultra-low attachment plates (Corning). After two days, the medium was changed to DMEM/F12 supplemented with 20% fetal bovine serum (FBS, HyClone) 2 mM L-glutamine, 0.1 mM β-mercaptoethanol, 0.1 mM NEAA. Two weeks after the initiation of embryoid body formation, the aggregates were cultured on gelatin coated plates to allow for attachment, outgrowth and further differentiation. Primary antibodies used for germ-layer evaluation included: mouse anti-human α-fetoprotein (Millipore, 1:250), rabbit anti-nestin (Millipore,1:250) and mouse anti-human α-smooth muscle actin (Millipore,1:500).

To assess the *in vivo* pluripotency of iPSC lines generated, teratoma formation assays were performed as previously described [62]. Four to six week old female NOD.CB17-*Prkdc*^{scid}/J mice (Jackson Laboratory) were injected subcutaneously into the dorsal flank with cells collected from one confluent six-well plate. Cells were harvested by incubation with collagenase IV (Sigma) and resuspended in DMEM/F12 medium supplemented with 30% Matrigel (BD Biosciences). Animals were monitored frequently and visible tumors were excised between eight to 12 weeks post-injection.

The tissues were fixed with 10% neutral buffered formalin, paraffin embedded, sectioned and stained with hematoxylin and eosin for histological evaluation. All animal procedures were approved by the Animal Care and Use Committee at Johns Hopkins University School of Medicine.

Assessment of HTT expression

For determination of HTT expression, cell lysates were prepared in RIPA buffer (1%NP-40, 0.1% SDS, 0.5% sodium deoxycholate in PBS) with protease inhibitor cocktail tablets (Roche). Protein concentrations were determined using the Pierce BCA protein assay kit (Thermo Scientific). To ensure separation of the wild-type and mutant HTT proteins, precast 3-8%Tris-Acetate gels (Invitrogen) were run at 70V for 30 minutes followed by 110V for 9 hours at 4°C. Western blot analysis was performed using mouse anti-HTT antibody (Millipore MAB 2166, 1:10000) and donkey anti-mouse HRP conjugated secondary antibodies (Jackson ImmunoResearch, 1:5000).

Neural differentiation of iPSCs and assessment of functionality

Neural differentiation of iPSCs was performed using two methods: a feeder-free and a feeder-dependent method. We used a modified version of a previously described feeder-free method [36]. Briefly, iPSCs were enzymatically detached from MEF by incubation with collagenase IV. The colonies were washed with PBS, re-suspended in hESM supplemented with 20 ng/ml of bFGF and cultured in suspension using ultra-low attachment plates. After five days, the medium was changed to a neural-induction medium consisting of neurobasal medium (Invitrogen) supplemented with 2% B27 (Invitrogen), 1% glutamine, and 40 ng/ml of bFGF. Partial media change was performed every second day and colonies were observed for a neurosphere morphology. For terminal differentiation into neurons, neural progenitor cells were mechanically dissociated by trituration to a single cell suspension and plated on poly-L-ornithine (Sigma, 20 μg/ml) and laminin (BD Biosciences, 10 μg/ml) coated coverslips in 24-well plates at a concentration of 30,000 cells/well. To initiate differentiation, dissociated neural progenitor cells were cultured in neural induction medium without bFGF (neural differentiation medium). Culture medium was changed every three to five days and cells were monitored frequently for neuronal growth. In the absence of bFGF, neuronal differentiation was observed at one week post-plating. To confirm neural differentiation, following primary antibodies were used: mouse anti-Nestin (Chemicon, 1:250), rabbit anti-β-tubulin (TUJ1; Sigma 1:2000), mouse anti-MAP2ab (Sigma, 1:250) and goat anti-DCX (Santa Cruz Biotechnology, 1:500).

For neural differentiation via the feeder-dependent method, the PA6 stromal cell line (RIKEN) was utilized according to a previously published protocol [37]. PA6 cells were maintained in Minimum essential medium alpha medium (Invitrogen) supplemented with 10% FBS and 1% penicillin-streptomycin (P/S). Once the stromal cell line had formed a confluent monolayer, it was used for neural differentiation. iPSCs were mechanically harvested from MEFs using the STEMPRO EZPassage tool (Invitrogen), washed with PBS and resuspended in neural induction medium consisting of Glasgow minimum essential medium (Invitrogen), 10% KOSR, 2 mM L-glutamine, 1 mM sodium pyruvate and 0.1 mM β-mercaptoethanol and 1% P/S. Small iPSCs colonies were seeded onto the PA6 monolayer and medium was changed every three days. The cultures were monitored daily for neuronal differentiation.

To assess neuronal function, electrophysiology of neurons derived from control iPSCs and HD-derived iPSCs was performed as previously described [39]. Neural progenitors derived by the feeder-free method were dissociated by trituration and single cells plated onto a layer of rat hippocampal astrocytes [47,63,64]. For whole-cell patch-clamp recordings, the patch pipette (3–7 MΩ) was filled with the following internal solution to record action potentials and mEPSCs: (in mM) K-gluconate 130, KCl 4, HEPES 10, EGTA 2, ATP 4, GTP 0.3, and phosphocreatine 7 (pH 7.3) and the external solution had the following composition (in mM): NaCl 140, KCl 3, $CaCl_2$ 2, $MgCl_2$ 1.3, HEPES 10, and glucose 10 (pH 7.4). For mEPSC recordings, 10 μM bicuculline and 1 μM tetrodotoxin was added to the external solution. An Axopatch 200B amplifier (Axon Instruments/Molecular Devices Corp., Union City, CA) was used for neuron recordings and analyzed using Clampfit 9.02 (Axon Instruments). Data were digitized at 10 kHz with a 2 kHz low-pass filter.

Transplantation of iPSC-derived neural progenitors and assessment of engraftment

GFP^+ neurospheres derived from the F-HD-iPSC line were mechanically dissociated into a single-cell suspension by trituration with a pipette tip. Cells were pelleted by centrifugation and re-suspended in Neurobasal medium at a concentration of 100,000 cells/μl. Four to six week-old female NOD.CB17-*Prkdc*^{scid}/J mice were used as transplantation recipients. Mice were anesthetized and 400,000 cells were stereotaxically injected into the subventricular zone of each mouse (4 μl/site; AP: 1 mm, ML: 1 mm, DV: 2 mm from Bregma). Mice were sacrificed at three, six and eight weeks of age to assess engraftment of the neural progenitor cells. Brain sections were prepared from transplanted mice and processed for immunostaining as described [65,66]. The following primary antibodies were used for immunohistochemistry: mouse anti-NeuN (Chemicon, 1:500), rabbit anti-GFP (1:1000) and mouse anti-human nuclei (HNA,Millipore, 1:100). Images were acquired on a META

multiphoton confocal system (Zeiss LSM 510) using a multi-track configuration. Procedures were performed in accordance with the Animal Care and Use Committee at Johns Hopkins University.

Astrocyte differentiation of iPSCs and characterization

Neurospheres derived using the feeder-free method were mechanically dissociated into a single cell suspension, filtered through a cell strainer and plated on poly-L-ornithine -laminin coated flasks. Cells were cultured in Astrocyte medium (ScienCell) and passaged as necessary. Once cells exhibited astrocyte morphology and formed a continuous monolayer, they were evaluated for the expression of astrocyte markers by immunocytochemistry using rabbit anti-GFAP (Dako, 1:500) and mouse anti-s100β (Sigma, 1:500). To quantify the number of astrocytes with cytoplasmic vacuolation, 600 randomly chosen cells were examined for each cell line and the average percentage of cells with vacuoles for four experiments was determined. Astrocytes were also examined for the presence of autophagosomes by immunostaining for the autophagy marker LC3 using rabbit anti-LC3 A/B (Cell Signaling, 1: 200). To induce autophagosome formation, astrocytes were treated with 50 μM chloroquine diphosphate (Invitrogen) overnight.

Transmission electron microscopy (TEM)

Cells were fixed in 2.5% glutaraldehyde, 3mM CaCl2, 1% sucrose, in 0.1 M sodium cacodylate buffer (pH 7.2) for one hour at RT. After a buffer rinse, samples were post-fixed in 1% osmium tetroxide in buffer (1 hour) on ice in the dark. Specimens were stained with 2% aqueous uranylacetate, dehydrated in a graded series of ethanol and embedded in Eponate 12 (Ted Pella) resin. Samples were polymerized at 60°C overnight. Ultrathin sections were prepared with a diamond knife on the Reichert-Jung Ultracut E ultramicrotome and picked up with naked 200 mesh copper grids. Grids were stained with 2% uranyl acetate in 50% methanol and cells were observed with a Hitachi 7600 TEM at 80 kV. Images were captured with an AMT CCD (1K x 1K) camera. TEM was performed at the Johns Hopkins Institute for Basic Biomedical Sciences microscope facility.

Additional file

Additional file 1: Figure S1. *In vitro* characterization of the D-HD-iPSCs. A: Expression of pluripotency markers. Immunostaining for the nuclear markers nanog and octamer-binding transcription factor 3/4 (OCT3/4) and the cell surface markers TRA 1-60 and stage specific embryonic antigen 4 (SSEA4) were positive. **B**: *In vitro* pluripotency was confirmed using an embryoid body assay to generate cells derived from the three major germ layers. Alpha-fetoprotein (AFP) positive cells representing endoderm, smooth muscle actin (SMA) expressing cells representing mesoderm and nestin positive cells representing ectoderm were identified. Scale bars: 100 μm. **C**: Western blot analysis confirmed the expression of mutant and wild-type HTT proteins in fibroblasts, iPSCs and neurospheres derived from the D-HD-iPSC. The hESC line H1 only expresses one band, corresponding to the wild-type protein.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

T.A.J., R.L.M, C.A.R., G.L.M. and H.S. conceived the study. T.A.J. led the project and performed the majority of experiments. W.R.K. performed the transplantation experiment. C.C. derived iPSC lines. H.Y. performed the electrophysiology analysis. R.L.M. and C.A.R. provided HD patient skin biopsy samples. T.A.J., G.L.M. and H.S. wrote the paper. All authors read and approve the manuscript.

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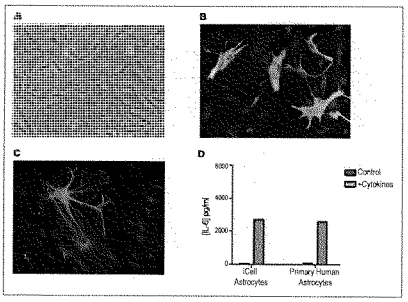
iCell® Astrocytes

iCell® Astrocytes from Cellular Dynamics International (CDI) are a heterogeneous population of human astrocytes derived from induced pluripotent stem cells. These cells provide a biologically relevant human model for drug discovery and disease research.

Astrocytes, the most abundant cell type in the central nervous system, create and maintain the brain architecture and perform various essential functions including brain homeostasis, distribution of energy substances, and synaptogenesis. In addition, recent research has shown that the loss of or changes in normal astrocyte functions play a critical role in neurological disorders and neurodegenerative diseases, such as Alzheimer's and Parkinson's diseases.

A more biologically relevant alternative to current cell models, iCell Astrocytes offer a reliable source of high quality, high purity human astrocytes for in vitro astrocyte-mediated neurotoxicity, targeted drug discovery, blood brain barrier modeling, and other life science research. These cells express the characteristic proteins, S100 calcium binding protein B (S100β) and glial fibrillary acidic protein (GFAP), and secrete trophic factors with stimulation.



▲ **Figure 1: iCell Astrocytes Exhibit Characteristics of Native Human Astrocytes**
A highly pure astrocyte population, iCell Astrocytes show (A) typical morphology and (B) expression of GFAP. Upon stimulation with TNFα, IL-1β, and IFNγ, iCell Astrocytes demonstrate (C) changes in cell morphology (stained with GFAP, green) and (D) upregulation of the IL-6 secretion, a pro-inflammatory cytokine.

Advantages

Applications

iCell Astrocytes are amenable to a variety of biochemical and cellular assays including:

- Astrocyte-mediated neurotoxicity
- Trophic factor secretion
- Co-culture environments

Specifications

Cell Type	Astrocytes
Organism	Human
Source	Differentiated from a CDI reprogrammed human iPS cell line
Quantity	>1.0 x 10^6 viable cells/unit
Shipped	Frozen
Storage	Liquid nitrogen
Media	None

Ordering Information

Product	Component(s)	Catalog #
iCell Astrocytes*	>1.0 x 10^6 viable cells	ASC-100-020-001-PT

* Currently available as a prototype product

For More Information

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sales@cellulardynamics.com
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CDI Products & Services

iCell Products
Provide access to biologically relevant, human iPS cells for disease modeling, drug discovery, toxicity testing, and regenerative medicine. CDI's rapidly growing portfolio of iCell products includes human cardiomyocytes, neurons, hepatocytes, endothelial cells, astrocytes, hematopoietic progenitor cells, skeletal myoblasts, dopaminergic neurons, and others.

Visit the CDI website for the most current list of supported cell types.

MyCell® Products
Include differentiated cells produced from disease-associated iPS cell lines, as well as iPS cell reprogramming, genetic engineering, and differentiation from customer-defined samples.

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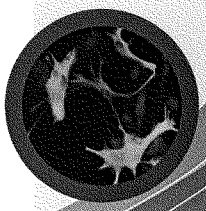
Master the use of iCell products by completing an iCertification Training Program. Attendees receive in-depth, interactive training on the handling and application of iCell products on cutting-edge technologies.



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iCell® Astrocytes

Uncover the Complex Role of Astrocytes in Health and Disease

Astrocytes are specialized glial cells and the most abundant cell type in the central nervous system (CNS), outnumbering neurons five-to-one. Astrocytes have historically been regarded as support cells for neural tissue, with reactive astrocytes serving as markers for damaged or diseased tissue. However, new studies reveal that astrocytes play an essential and complex role in the maintenance of a healthy CNS and in the onset and development of CNS disease.

CDI's iCell® Astrocytes are human iPS cell-derived astrocytes. They provide a readily accessible, consistent, and biologically relevant source of astrocytes for the study of synaptic transmission and plasticity in normal CNS function and disease progression. Benefits include:

- >95% pure population of human astrocytes
- Expression of relevant astrocyte markers (e.g. S100β and GFAP)
- Exhibition of cytokine-mediated inflammatory responses
- Limited proliferative capacity and long-term viability
- Ability to co-culture with human neurons

Enhance the Relevance of Your Neuroscience Models

Assayed as a pure culture of astrocytes or as a co-culture with other iCell neural cell types, iCell Astrocytes provide multiple layers of biologic complexity to enable the interrogation of the following:

NORMAL CNS FUNCTIONS

- Synaptic remodeling and pruning
- Neurotransmitter homeostasis
- Neural network communication
- Blood-brain barrier support
- Regulation of CNS blood flow
- CNS metabolism

DISEASE CNS FUNCTIONS

- Reactive astrogliosis and CNS inflammation
- Alexander disease and leukodystrophies

- Neurodegenerative disease
- Multiple sclerosis and autoimmune inflammatory disorders

Ordering Information

Catalog #	Description	Quantity	
ASC-100-020-001-PT	iCell Astrocytes Cryopreserved iCell Astrocytes * Currently available as a prototype product	>1 x 10^6 Viable Cells/Vial	REQUEST QUOTE

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Research Paper

Human iPS cell-derived astrocyte transplants preserve respiratory function after spinal cord injury

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ABSTRACT

Transplantation-based replacement of lost and/or dysfunctional astrocytes is a promising therapy for spinal cord injury (SCI) that has not been extensively explored, despite the integral roles played by astrocytes in the central nervous system (CNS). Induced pluripotent stem (iPS) cells are a clinically-relevant source of pluripotent cells that both avoid ethical issues of embryonic stem cells and allow for homogeneous derivation of mature cell types in large quantities, potentially in ao autologous fashion. Despite their promise, the iPS cell field is in its infancy with respect to evaluating *in vivo* graft integration and therapeutic efficacy in SCI models. Astrocytes express the major glutamate transporter, GLT1, which is responsible for the vast majority of glutamate uptake in spinal cord. Following SCI, compromised GLT1 expression/function can increase susceptibility to excitotoxicity. We therefore evaluated intraspinal transplantation of human iPS cell-derived astrocytes (hIPSAs) following cervical contusion SCI as a novel strategy fnr reconstituting GLT1 expression and fnr protecting diaphragmatic respiratory neural circuitry. Transplant-derived cells shnwed robust long-term survival post-injection and efficeotly differentiated into astrocytes in injured spinal cord of both immunesuppressed mice and rats. However, the majority of transplant-derived astrocytes did not express high levels of GLT1, particularly at early times post-injection. To enhance their ability to modulate extracellular glutamate levels, we engineered hIPSAs with lentivirus to constitutively express GLT1. Overexpression significantly increased GLT1 protein and functional GLT1-mediated glutamate uptake levels in hIPSAs both *in vitro* and *in vivo* post-transplantation. Compared to human fibroblast control and unmodified hIPSA transplantatioo, GLT1-overexpressing hIPSAs reduced (1) lesion size within the injured cervical spinal cord, (2) morphological denervation by respiratory phrenic motor neurons at the diaphragm neuromuscular junction, and (3) functional diaphragm denervation as measured by recording of spontaneous EMGs and evoked compound muscle action potentials. Our findings demonstrate that hIPSA transplantation is a therapeutically-powerful approach for SCI.

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1. Introduction

Transplantation of neural stem cells (NSCs) and neural progenitor cells (NPCs) is a promising therapeutic strategy for both neurodegenerative diseases of the central nervous system (CNS) and traumatic CNS injury, including spinal cord injury (SCI), because of the ability to replace lost and/or dysfunctional nervous system cell types, promote neuroprotection, deliver gene factors of interest and provide other benefits (Gage, 2000).

Initial trauma following SCI results in immediate cell death and axotomy of passing fibers. Contusion- and compression-type injuries, the predominant forms of traumatic SCI observed in the clinical population, are followed by an extended period of secondary cell death and consequent exacerbation of functional deficits (McDonald and Becker,

Abbreviations: SCI, spinal cord injury; iPS cells, induced pluripotent stem cells; hIPSAs, human induced pluripotent stem cell-derived astrocytes; GLT1, glutamate transporter 1; PhMN, phrenic motor neuron; C3 (4 5, *etc.*), cervical spinal cord level 3 (4, 5, *etc.*); GRP, glial-restricted precursor; CMAP, compound muscle action potential; NMJ, neuromuscular junction; GFP-hIPSA, lentivirus-GFP transduced hIPSA; GLT1-hIPSA, lentivirus-GLT1 transduced hIPSA; GFP-hFibro, lentivirus-GFP transduced human fibroblast; LV-GFP, lentivirus-GFP; LV-GLT1, lentivirus-GLT1.

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2003). One of the major causes of secondary degeneration following SCI is excitotoxic cell death due to dysregulation of extracellular glutamate homeostasis (Park et al., 2004; Stys, 2004). Exogenous parenchymal administration of glutamate to uninjured spinal cord results in tissue and function loss similar to SCI (Xu et al., 2005). While large increases in glutamate can occur shortly after SCI, elevation can also persist depending on injury severity (Liu et al., 1991; Panter et al., 1990; Xu et al., 2004). In addition to focal increases, levels can also rise in regions removed from the lesion site, possibly *via* a spreading mechanism involving activated glia (Hulsebosch, 2008). Early gray matter loss is likely mediated by NMDA receptors, while delayed loss of neurons and oligodendrocytes, as well as axonal and myelin injury, is thought to be predominantly mediated *via* AMPA over-activation (Stys, 2004). A valuable opportunity therefore exists after SCI for preventing cell injury and functional loss that occur during secondary degeneration. Importantly, secondary degeneration is a relevant therapeutic target given its relatively prolonged time window.

Glutamate is efficiently cleared from the synapse and other sites by transporters located on the plasma membrane (Maragakis and Rothstein, 2004). Astrocytes are supportive glial cells that play a host of crucial roles in CNS function (Pekny and Nilsson, 2005). Astrocytes express the major CNS glutamate transporter, GLT1, which is responsible for the vast majority of functional glutamate uptake and plays a central role in regulation of extracellular glutamate homeostasis in the spinal cord (Maragakis and Rothstein, 2006). Following SCI, astrocyte loss and/or altered GLT1 expression, function and localization can result in further susceptibility to excitotoxicity. For example, we previously found that in rodent models of unilateral mid-cervical (C4) contusion SCI, numbers of GLT1-expressing astrocytes, total intraspinal GLT1 protein expression and GLT1-mediated functional glutamate uptake in ventral horn are reduced soon after injury and this reduction persists chronically (Li et al., 2015). Astrocytes have traditionally been viewed in a negative light following CNS trauma because of their association with disease mechanisms such as glial scarring and pro-inflammatory cytokine release. However, their crucial neuroprotective/homeostatic roles, including GLT1-mediated glutamate uptake, have not been extensively targeted in SCI models using approaches such as NSC and NPC transplantation, despite obvious therapeutic implications (Maragakis and Rothstein, 2006).

Transplantation-based targeting of astrocytes provides a number of key benefits. Grafts can be anatomically delivered to precise locations for achieving neuroprotection of specific populations of cells (Lepore et al., 2008b). Alternative strategies such as gene therapy only target one/several specific genes (s), while astrocyte transplantation can participate in the restoration of a host of astrocyte functions. Transplantation also provides for long-term astrocyte integration and therapeutic replacement. For example, the lasting nature of dysregulation of extracellular glutamate homeostasis after SCI (Lepore et al., 2011a,2011c) calls for longer-term maintenance of therapeutic effects, both with respect to early cell loss occurring during secondary degeneration and outcomes of SCI associated with more persistent pathophysiology of glutamate signaling such as chronic neuropathic pain (Gwak et al., 2012; Hulsebosch, 2008).

To achieve translation of NSC/NPC-based interventions, clinically-relevant cell sources that address scientific, practical and ethical considerations must be extensively tested in relevant models of CNS disease. These cell types also need to be evaluated in the context of patient-relevant functional outcomes such as respiratory function. Induced pluripotent stem (iPS) cells are pluripotent cells generated from adult somatic cell types *via* expression of combinations of pluripotency-related factors, avoiding ethical issues of embryonic stem cells (Takahashi et al., 2007b). This technology allows for homogeneous derivation of cell types in large quantities for applications such as transplantation, potentially in an autologous fashion from the eventual recipient or from allogeneic sources (Das and Pal, 2010; Kiskinis and Eggan, 2010). Despite the promise of this approach, the iPS cell transplantation field is still in the early stages of evaluating therapeutic usefulness in relevant SCI models (Salewski et al., 2010).

Respiratory compromise is a major problem following cervical spinal cord trauma. Cervical SCI represents greater than half of all human cases, in addition to often resulting in the most severe physical and psychological debilitation (Lane et al., 2008). Respiratory compromise is the leading cause of morbidity and mortality following SCI. While a growing literature exists on respiratory function in animal models of SCI (Lane et al., 2008, 2009), few studies have examined cellular mechanisms involved in protection of this vital neural circuitry, and little work has been conducted to test therapies for targeting cervical spinal cord-related functional outcome measures such as breathing. Phrenic motor neuron (PhMN) loss plays a central role in respiratory compromise following cervical SCI. The diaphragm, a major inspiratory muscle, is innervated by PhMNs located at cervical levels 3–5 (Lane et al., 2009). PhMN output is driven by descending pre-motor bulbospinal neurons in the medullary rostral ventral respiratory group (rVRG) (Zimmer et al., 2007). Cervical SCI results in diaphragmatic respiratory compromise due to PhMN loss and/or injury to descending bulbospinal respiratory axons. The majority of these injuries affect mid-cervical levels (Shanmuganathan et al., 2008) (the location of the PhMN pool), and respiratory function following mid-cervical SCI is significantly determined by PhMN loss/sparing (Strakowski et al., 2007). Although use of thoracic models has predominated, cervical SCI animal models have recently been developed (Aguilar and Steward, 2010; Awad et al., 2013; Gensel et al., 2006; Lane et al., 2012; Lee et al., 2010; Sandrow-Feinberg et al., 2009, 2010; Sandrow et al., 2008; Stamegna et al., 2011), including our own (Nicaise et al., 2012). Because of the relevance of astrocyte and GLT1 dysfunction to PhMN loss/injury following cervical trauma, we targeted transplantation in the present study to cervical spinal cord ventral horn in a cervical contusion SCI model.

We previously investigated the therapeutic efficacy of transplanting rodent-derived glial-restricted precursors (GRP), a class of lineage-restricted astrocyte progenitor cell (Li et al., 2014). We transplanted either undifferentiated GRPs or GRP-derived astrocytes (pre-differentiated *in vitro* prior to injection) into our model of cervical contusion SCI, and found that both cell types survived, localized to the ventral horn and efficiently differentiated into mature astrocytes. However, animals injected with GRP-derived astrocytes had higher levels of intraspinal GLT1 expression than those injected with undifferentiated GRPs, suggesting that pre-differentiation enhanced the *in vivo* maturation of these cells. We also observed that modifying GRP-derived astrocytes to constitutively express GLT1 was more effective in achieving *in vivo* GLT1 expression and for protecting PhMNs.

Given the importance of astrocytes in SCI pathogenesis, the observations of GLT1 dysfunction following SCI, and our previous success targeting astrocyte GLT1 using rodent-derived glial progenitor cells, in the present study we evaluated intraspinal transplantation of hiPS cell-derived astrocytes (hIPSAs) into ventral horn following cervical contusion SCI as a novel therapeutic strategy for reconstituting GLT1 function. Specifically, we examined the *in vivo* fate of hIPSAs transplants in the injured spinal cord of both mouse and rat models of cervical contusion SCI, including long-term survival and integration, astrocyte differentiation, maturation into GLT1-expressing cells and safety. We also tested the therapeutic efficacy of hIPSA transplantation for protection of PhMNs and preservation of diaphragm function.

Derivation of cell types from iPS cells represents a relevant approach for clinical translation; therefore, it is critical to test both the safety and efficacy of these transplants in a patient-relevant SCI model. Importantly, previous work has shown that human- and rodent-derived versions of a given stem/progenitor type do not necessarily show similar *in vivo* fate or therapeutic properties in the disease nervous system. For example, we previously demonstrated that, following transplantation into the $SOD1^{G93A}$ rodent model of ALS, human glial progenitors cells show more persistent proliferation, greater migratory capacity, reduced efficiency of astrocyte differentiation, and decreased GLT1 expression

compared to their rodent counterparts, which resulted in a lack of therapeutic efficacy only with the human cells (Lepore et al., 2008b, 2011b). It is therefore important to extend our previous studies with rodent-derived glial progenitors in the cervical contusion SCI model to now test human iPS cells.

2. Materials and methods

2.1. Animals

2.1.1. Transplantation into rats and mice

Female Sprague–Dawley rats weighing 250–300 g were purchased from Taconic Farm (Rockville, MD). Female C57BL/6 wild-type mice weighing 20–30 g were purchased from The Jackson Laboratory (Bar Harbor, ME). All animals were housed in a humidity-, temperature-, and light-controlled animal facility with *ad libitum* access to water and food. Experimental procedures were approved by the Thomas Jefferson University IACUC and conducted in compliance with ARRIVE (*Animal Research: Reporting of In Vivo Experiments*) guidelines.

2.2. Cervical contusion SCI

2.2.1. Rat SCI

Rats were anesthetized with ketamine (100 mg/kg), xylazine (5 mg/kg) and acepromazine (2 mg/kg). The cervical dorsal skin and underlying muscles were incised. The paravertebral muscles overlying C3–C5 were removed. Following unilateral laminectomy on the right side at C3, C4 and C5 levels, rats were subjected to a C4 spinal contusion injury with the Infinite Horizon impactor (Precision Systems and Instrumentation, Lexington, KY) using a 1.5 mm tip at a force of 395 kdyn. This injury paradigm is based on our previously published rat model that results in robust PhMN degeneration and chronic diaphragm dysfunction (Nicaise et al., 2012, 2013). Rats were transplanted in all studies immediately following injury. After surgical procedures, overlying muscles were closed in layers with sterile 4–0 silk sutures, and the skin incision was closed using wound clips. Animals were allowed to recover on a circulating warm water heating pad until awake and then returned to their home cages. They were monitored daily until sacrifice, and measures were taken to avoid dehydration and to minimize any pain or discomfort.

2.2.2. Mouse SCI

Mice were anesthetized with a cocktail of ketamine (120 mg/kg) and xylazine (5 mg/kg). The surgical procedure and post-surgical monitoring used for mice were the same as described above for rats. For the contusion injury, the 1 mm impactor tip was raised 1.25 mm above the dura prior to impact, and a force of 50 kdyn (kdyn) was used for impact.

2.3. Virus production

Lentiviral vector carrying the green fluorescent protein (GFP) gene or GLT1 gene was packaged in 293FT cells. Briefly, to produce control lentiviral-GFP vector, 293FT cells were transfected with pCDH-MSCV-MCS-EF1-GFP plasmid (System Biosciences, Mountain View, CA) and three other helper plasmids, pLP-1, pLP-2, and pLP/VSVG with Polyfect (Qiagen, Valencia, CA). To produce lentiviral-GLT1 vector, GLT1 gene CDS fragment was inserted into MCS of pCDH-MSCV-MCS-EF1-GFP plasmid, and the vector plasmid was then transfected into 293FT cells with three helper plasmids as described above. Supernatant was collected 72 h later, and lentiviral vector was concentrated with PEG-it Virus Precipitation Solution (System Biosciences, Mountain View, CA) and re-suspended with PBS to the final titer of 1×10^8 infectious units/ml.

2.4. Human induced pluripotent stem cell derived astrocytes

2.4.1. Human iPS cell derivation, culturing and astrocyte differentiation

iPS cells were derived from non-diseased healthy patient donors. Dermal fibroblasts were reprogrammed into iPS cells *via* retroviral transduction with KLF4, SOX2, OCT4, and c-MYC (Takahashi et al., 2007a). By immunohistochemistry and qRT-PCR, these putative iPS cells expressed proteins and transcripts associated with pluripotency, including Sox 2, and stem cell-associated antigens, including SSEA4, Nanog, alkaline phosphatase, and TRA 1–81, and capacity to differentiate into cells of three germ layers was established. Finally, the karyotype of these iPS cells was found to be normal. Once pluripotent iPS cells were generated, the stem cells were cultured in E8 medium (Life Technologies, Grand Island, NY). To maintain optimum pluripotency and limit spontaneous differentiation, the stem cell colonies were manually cleaned once every 6 days just before passage using dispase (Stem Cell Technologies, Vancouver, BC). To differentiate the iPS cells into astrocytes, a protocol previously described by Haidet-Phillips and colleagues (Haidet-Phillips et al., 2014) was used. To summarize, iPS cells were lifted with dispase, gently separated into single cells and plated as a monolayer. Using the smad dual inhibition pathway method to direct differentiation toward a neural phenotype, the cells were incubated in DMEM/F12 (Life Technologies, Grand Island, NY) enriched with 0.2 μM LDN (Stemgent, Cambridge, MA) and 10 μM SB431542 (Sigma, Saint Louis, MO). The cells were then exposed to 1 μM retinoic acid (Sigma, Saint Louis MO) and N2 (Life Technologies, Grand Island, NY) starting at day 5 and Sonic HedgeHog (Life Technologies, Grand Island, NY) starting at day 8. From day 15 to day 30 after starting the differentiation protocol, the medium was gradually changed to neurobasal medium. After day 30, to differentiate these iPS cell-derived glial progenitors into astrocytes, cells were maintained and expanded in DMEM/F12 supplemented with 1% Fetal Bovine Serum, B27, L-glutamine, non-essential amino acids, penicillin/streptomycin (all from Life Technologies, Grand Island, NY) and 2 μg/ml Heparin (Sigma-Aldrich, St. Louis, MO) for an additional 60 days. Astrocytes derived from human iPS were identified with immunostaining using GFAP antibody. For feeding and passaging of astrocyte progenitor cultures, cells were rinsed with PBS and incubated with 4 ml of 0.05% trypsin for 5 min. Cells were collected in trypsin and rinsed with 7 ml of culture medium and 1× trypsin inhibitor (Life Technologies, Grand Island, NY) to stop trypsinization. Cells were centrifuged at 1000 rpm for 5 min and re-suspended in fresh culture medium. Cells were counted and seeded onto poly-L-lysine coated dishes. Cells were fed twice a week and were passaged after they were 80%–90% confluent.

2.4.2. GLT1 overexpression

After differentiation for 90 days, hIPSAs (astrocytes derived from human iPS cells) were transduced with lentiviral-GFP vector or lentiviral-GLT1 vector, at the concentration of 1×10^6 infectious units/ml, one week before transplantation. On the second day of transduction, culture medium was changed and the cells were cultured for 5 more days.

2.5. Human dermal fibroblasts

Human dermal fibroblast cells (ATCC, Manassas, VA) were cultured with Fibroblast Growth Kit-low serum (ATCC, Manassas, VA). Fibroblasts were transduced with control lentiviral-GFP vector one week before transplantation. Transduced GFP was used to track transplanted cells *in vivo*.

2.6. Transplantation

2.6.1. Cell preparation for transplantation

On the day of transplantation, cells were rinsed with PBS and trypsinized with 0.05% trypsin, collected and rinsed with culture

medium and 1 × trypsin inhibitor. The cells were washed with artificial cerebrospinal fluid twice. Cell viability was assessed using the trypan blue assay and was always found to be greater than 80%. The final cell concentration was adjusted to 1×10^8 cells/ml.

2.6.2. Intraspinal transplantation

Transplantation was conducted on deeply anesthetized rats and mice immediately post-injury. Following unilateral right-sided contusion injury at C4, cells were injected into the spinal cord at two locations. Each site contained 2 μl of cell suspension, which was administered into the spinal cord ventral horn using a Hamilton gas-tight syringe mounted on an electronic UMP3 micropump (World Precision International, Sarasota, FL) (Lepore and Maragakis, 2011; Lepore et al., 2011a). The sites of injections were located at the rostral and caudal edges of the contusion site. Ventral horns were targeted by lowering the 33-gauge 45-degree beveled needle 1.5 mm below the dorsal surface of the spinal cord. Each injection was delivered at a constant rate over 5 min. Upon completion of cell delivery, overlying muscles were then closed in layers with sterile 4–0 silk sutures, and the skin incision was closed using sterile wound clips. Animals were allowed to recover and monitored daily.

2.6.3. Immune suppression

All animals were immune suppressed. Rats received subcutaneous administration of cyclosporine A (10 mg/kg; Sandoz Pharmaceuticals, East Hanover, NJ) daily beginning three days before grafting and continuously until sacrifice. Mice were given both FK-506 and rapamycin (1 mg/kg each; LC Laboratories; Woburn, MA).

2.7. Tissue processing for histology

At the time of sacrifice, animals were anesthetized, and diaphragm muscle was freshly removed prior to perfusion and then further processed for neuromuscular junction (NMJ) labeling. Animals were transcardially perfused with 0.9% saline, followed by 4% paraformaldehyde infusion. Spinal cords were harvested, then cryoprotected in 30% sucrose for 3 days and embedded in freezing medium. Spinal cord tissue blocks were cut serially in the sagittal or transverse planes at a thickness of 30 μm. Sections were collected on glass slides and stored at −20 °C until analysis. Spinal cord sections were thawed, allowed to dry for 1 h at room temperature, and stained with 0.5% Cresyl violet acetate according to standard procedure (Nicaise et al., 2012).

2.8. Immunohistochemistry

Frozen spinal cord sections were air-dried, washed with PBS, permeabilized with 0.4% Triton X-100 in PBS for 5 min at room temperature, and then incubated in blocking solution (PBS containing 10% normal goat serum and 0.4% Triton X-100) for 1 h at room temperature. Sections were labeled overnight at 4 °C with the primary antibodies in blocking solution. Sections were then washed three times with PBS (5 min per wash) and incubated with secondary antibodies in blocking solution for 1 h at room temperature. After washing twice with PBS (10 min per wash), sections were cover-slipped. A number of primary antibodies were used. Mouse anti-GFAP antibody (EMD Millipore Corporation, Billerica, MA; 1:200) and rabbit anti-GFAP antibody (Dako North America, Carpinteria, CA; 1:200) were used to label astrocytes (Lepore et al., 2008a). Mouse anti-human GFAP antibody (StemCells, Inc, Newark, CA; 1:200) was used to label astrocytes of human origin in mice and rats. Rabbit anti-GLT1 (1:800) and mouse anti-GLT1 (1:200) were used to label GLT1 protein (both were provided by Jeffrey Rothstein's laboratory) (Lepore et al., 2008b). Rabbit anti-Ki67 (Thermo Fisher Scientific, Rockford, IL; 1:200) labeled proliferating cells (Lepore et al., 2008a). Mouse anti-human cytoplasmic marker antibody (StemCells, Inc, Newark, CA; 1:200) and mouse anti-HuNu antibody (EMD Millipore Corporation, Billerica, MA; 1:200) were used to label human cytoplasm and human nuclear antigen, respectively, for selectively identifying human-derived cells. Secondary antibodies included: FITC goat-anti-mouse IgG, FITC goat-anti-rabbit IgG, TRITC goat-anti-mouse IgG, TRITC goat-anti-rabbit IgG, Alexa Fluor 647 goat-anti-mouse IgG, Alexa Fluor 647 goat-anti-rabbit IgG. All secondary antibodies (Jackson ImmunoResearch Laboratories, West Grove, PA) were diluted at 1:200 to recognize the matched primary antibody. For fluorescence analysis, sections were cover-slipped with fluorescent-compatible mounting medium (ProLong Gold, Life Technologies, Grand Island, NY).

2.9. Quantification of in vitro cultured cell differentiation, proliferation and GLT1 expression

The proportions of $GFAP^+$ astrocytes and $Ki67^+$ proliferating cells were expressed as a percentage of the total number of cultured cells (labeled by DAPI). In order to quantify double-labeling of DAPI with GFAP or Ki67, images were taken at 10× magnification and analyzed using ImageJ software. In each image, cells with a $DAPI^+$ nucleus were assessed for expression of GFAP or Ki67.

2.10. Quantification of transplant differentiation

Rats and mice were sacrificed for quantification of astrocyte differentiation ($GFAP^+$) and proliferation ($Ki67^+$). The proportions $GFAP^+$ astrocytes and $Ki67^+$ proliferating cells were expressed as a percentage of the total number of transplanted human cells (labeled by anti-hCytoplasm or HuNu antibody). In order to quantify double-labeling of hCytoplasm or HuNA with GFAP and Ki67, double-labeled transverse sections were imaged at 10× magnification using MetaMorph software and were then analyzed using ImageJ software. In each image, cells expressing hCytoplasm or HuNu were assessed for co-expression of GFAP or Ki67.

2.11. Quantification of GLT1 expression by transplants

Rats and mice were sacrificed for quantification of GLT1 expression by hCyto-labeled cells in the ventral horn. $GLT1^+$ and $hCyto^+$ cells were identified in the ventral horn using ImageJ software, and the percentage of $hCyto^+$ cells (representing any transplant-derived cell) that co-expressed GLT1 were quantified.

2.12. Lesion imaging and quantification

Images were acquired with a Zeiss Imager M2 upright microscope and analyzed with ImageJ software. Lesion size was quantified in Cresyl violet stained sections (Li et al., 2015). Specifically, lesion area was determined in every 10th section by tracing both the total area of the hemi-spinal cord ipsilateral to the contusion site and the actual lesion area. Lesion was defined as areas including both lost tissue (cystic cavity formation) and surrounding damaged tissue in which the normal anatomical structure of the spinal cord was lost. The lesion epicenter was defined as the section with the largest percent lesioned tissue (relative to total tissue area in the same section).

2.13. Neuromuscular junction (NMJ) analysis

Fresh hemi-diaphragm muscle was dissected from each animal for whole-mount immunohistochemistry, as described previously (Wright et al., 2007). Hemi-diaphragm muscle was dissected, stretched, pinned down to Sylgard medium (Fisher Scientific, Pittsburgh, PA), and extensively cleaned to remove any connective tissue to allow for antibody penetration. Motor axons and their terminals were labeled with SMI-312R (Covance, Princeton, NJ; 1:1000) and

SV2-s (DSHB, Iowa City, IA; 1:10), respectively, and both primary antibodies were detected with FITC anti-mouse IgG secondary (Jackson ImmunoResearch Laboratories, West Grove, PA; 1:100). Postsynaptic acetylcholine receptors were labeled with rhodamine-conjugated alpha-bungarotoxin (Life Technologies, Grand Island, NY; 1:400). Labeled muscles were analyzed for total numbers of NMJs and intact, denervated and multiply-innervated NMJs. Whole-mounted diaphragms were imaged on a FluoView FV1000 confocal microscope (Olympus, Center Valley, PA). We only conducted NMJ analysis in ipsilateral hemi-diaphragm because in our previously published work we did not observe denervation or sprouting in contralateral hemi-diaphragm after cervical hemi-contusion SCI (Nicaise et al., 2012).

2.14. Functional glutamate uptake assay

After transduction with lentiviral-GFP vector or lentiviral-GLT1 vector, hIPSAs were cultured for 10 days. Human fibroblasts transduced with lentiviral-GFP vector were used as control. Glutamate uptake activity was measured as previously described (Dowd and Robinson, 1996), with slight modification. Briefly, cells were washed and pre-incubated with either a sodium- or choline-containing uptake buffer (in mM: Tris, 5; HEPES, 10; NaCl or choline chloride, 140; KCl, 2.5; CaCl2, 1.2; $MgCl_2$, 1.2; K2HPO_4, 1.2; glucose, 10) for 20 min at 37 °C; and in DHK treatment groups, 100 μM of DHK was added to inhibit GLT1. The uptake buffer was then replaced with fresh uptake buffer containing 20 nM ^{3}H-glutamate (49 Ci/mmol; PerkinElmer, CA) and 20 μM unlabeled glutamate. The cells were incubated for 5 min at 37 °C. The reaction was terminated by washing cells three times with choline-containing uptake buffer containing 2 mM unlabeled glutamate, followed by immediate lysis in ice-cold 0.1 N NaOH. Cell extracts were then measured with a liquid scintillation counter (Beckman Instruments, Fullerton, CA). The protein content in each well was measured using the Bradford protein assay (Bio-Rad, Hercules, CA).

2.15. Diaphragm compound muscle action potentials (CMAPs)

Rats were anesthetized in the same manner described above. Phrenic nerve conduction studies were performed with single stimulation (0.5 ms duration; 6 mV amplitude) at the neck *via* near nerve needle electrodes placed along the phrenic nerve (Li et al., 2015; Nicaise et al., 2012). The ground needle electrode was placed in the tail, and the reference electrode was placed subcutaneously in the right abdominal region. Recording was obtained *via* a surface strip along the costal margin of the diaphragm, and CMAP amplitude was measured baseline to peak. Recordings were made using an ADI Powerlab 8/30 stimulator and BioAMP amplifier (ADInstruments, Colorado Springs, CO), followed by computer-assisted data analysis (Scope 3.5.6, ADInstruments). For each animal, 10–20 tracings were averaged to ensure reproducibility.

2.16. Spontaneous EMG recordings

Prior to being euthanized, animals received a laparotomy. These EMG recordings were terminal experiments and were only conducted immediately prior to euthanasia. Bipolar electrodes spaced by 3 mm were inserted into specific sub-regions of the right hemi-diaphragm (*i.e.* dorsal, medial or ventral regions) (Li et al., 2015). Activity was recorded and averaged during spontaneous breathing at each of these 3 locations separately in each animal. The EMG signal was amplified, filtered through a band-pass filter (50–3000 Hz), and integrated using LabChart 7 software (ADInstruments). Parameters such as inspiratory bursts per minute, discharge duration and integrated peak amplitude were averaged over 2 min sample periods. No attempt was made to control or monitor the overall level of respiratory motor drive during the EMG recordings.

2.17. Statistics

Results were expressed as means ± standard error of the mean (SEM). A Kolmogorov–Smirnov test was conducted for all variables to assess normality. Unpaired *t* test or Mann–Whitney was used to assess statistical significance between two groups. With respect to multiple comparisons involving three groups or more, statistical significance was assessed by analysis of variance (one-way ANOVA) followed by *post-hoc* test (Bonferroni's method). Statistics were computed with Graphpad Prism 5 (GraphPad Software, Inc., La Jolla, CA). $p < 0.05$ was considered as statistically significant.

3. Results

3.1. In vitro characterization of human iPS cell-derived astrocytes (hIPSAs)

We differentiated human iPS cells into astrocytes by culturing them in differentiating medium containing FBS. We transduced cells with lentivirus (LV)-GFP or LV-GLT1-GFP to generate control cells (GFP–hIPSAs) and GLT1-overexpressing hIPSAs (GLT1–hIPSAs), respectively. The GFP–hIPSAs expressed little-to-no GLT1 protein (Fig. 1A, C), consistent with the limited expression of GLT1 by cultured astrocytes in the absence of neuronal co-culture (Li et al., 2014; Perego et al., 2000), while GLT1–hIPSAs expressed high levels of GLT1 protein *in vitro* (Fig. 1B, C). In addition, the vast majority of DAPI$^+$ GLT1–hIPSAs expressed GLT1 (Fig. 1B), which is expected given the high efficiency of transduction with our lentivirus (not shown). GLT1 overexpression did not alter hiPSA differentiation (Fig. 1D, E, H) or proliferation (Fig. 1F–H). In addition to significantly increased GLT1 protein expression levels, GLT1–hIPSAs showed a large increase in functional GLT1-mediated glutamate uptake compared to GFP–hIPSAs using an *in vitro* ^{3}H-glutamate uptake assay (Fig. 1J). In this ^{3}H-glutamate uptake assay and in the subsequent transplantation experiments, we used LV-GFP transduced human fibroblasts (GFP–hFibro) (Fig. 1I) as a non-glial cell control.

3.2. Human iPSA transplants robustly survived and differentiated into astrocytes following rat cervical contusion SCI

We characterized the fate of transplanted hIPSAs in both rats and mice following unilateral C4 contusion SCI, given the usefulness of both experimental models for studying nervous system diseases. Immediately following injury, we injected hIPSAs directly into the ventral horn at locations just rostral and caudal to the contusion site (Fig. 2A). We specifically delivered cells into the ventral horn to anatomically target the location of the PhMN pool (Fig. 2B).

We sacrificed rats at 2 days, 2 weeks and 4 weeks post-injury/transplantation. Double-labeling with panGFAP antibody and a human-specific GFAP antibody demonstrated that transplanted human-derived cells differentiated into astrocytes (Fig. 2C). Both transplanted GFP–hIPSAs (Fig. 2D, F, H) and GLT1–hIPSAs (Fig. 2E, G, I) robustly survived out to W4, and nearly all hCytoplasm$^+$ transplant-derived cells co-labeled with the astrocyte lineage marker, GFAP, at D2 (Fig. 2D–E), W2 (Fig. F–G) and W4 (Fig. 2H–I). There were no differences in the degree of astrocyte differentiation between GFP–hIPSAs and GLT1–hIPSAs at any of these time points (quantification shown in Fig. 2J). LV-GFP transduced human fibroblasts (GFP–hFibro) also survived in the injured spinal cord to at least W4 post-injury (Fig. 2K).

Despite efficient astrocyte differentiation, only a small percentage of GFP–hIPSA transplant-derived cells expressed GLT1 protein in the injury site at D2 (Fig. 3A), W2 (Fig. 3C) and W4 (Fig. 3E). On the contrary, the majority of GLT1–hIPSAs robustly expressed GLT1 at all times (Fig. 3B, D, and F) (quantification: Fig. 3G).

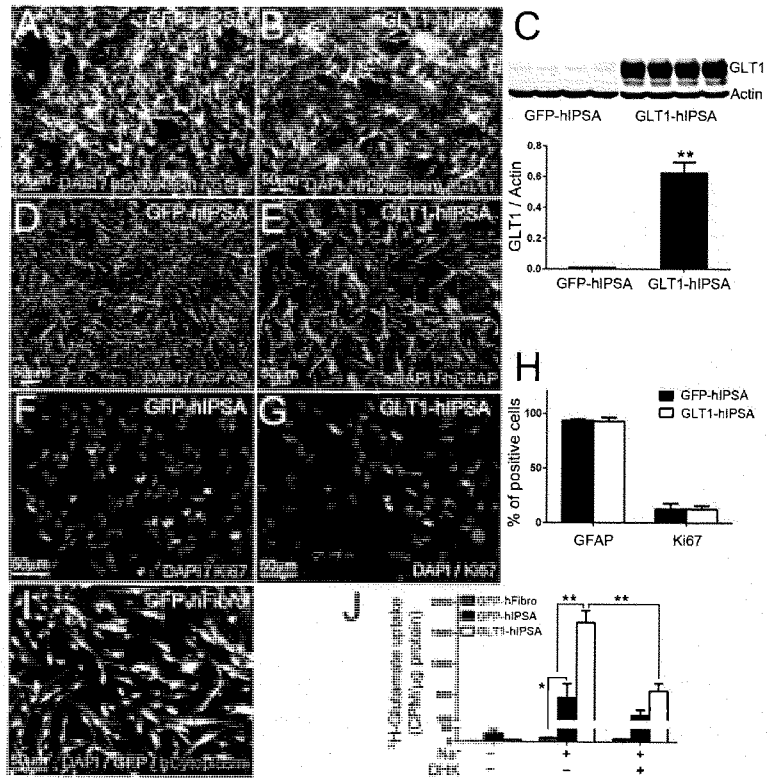

Fig. 1. *In vitro* characterization of human iPS cell-derived astrocytes (hIPSAs). Cells were transduced with lentivirus (LV)-GFP or LV-GLT1-GFP to generate control GFP-hIPSAs and GLT1-overexpressing hIPSAs (GLT1-hIPSAs), respectively. Human cytoplasm$^+$ GFP-hIPSAs expressed little-to-no GLT1 protein (A), while GLT1-hIPSAs expressed high levels of GLT1 protein *in vitro* (B), which was further confirmed with immunoblotting analysis (C, *lower*: quantification result). Following infection with either virus, astrocyte differentiation was determined by the percentage of cells expressing the astrocyte lineage marker, GFAP (D–E). Proliferation was determined by the percentage of cells expressing the proliferation marker, Ki67 (F–G). Quantification results of cell differentiation and proliferation are shown in (H). Human fibroblasts, which were transduced with LV-GFP vector (GFP-hFibro) (I), were used as non-glial control in the glutamate uptake assay and *in vivo* transplantation experiments. ^{3}H-glutamate uptake assay was performed to detect GLT1 function. GLT1-hIPSAs showed a large increase in Na^+ dependent glutamate uptake compared to GFP-hFibro and GFP-hIPSAs. This increased uptake was blocked with GLT1 specific inhibitor, DHK, at the concentration of 100 μmol/l (J). Results were expressed as means ± SEM. $^*p < 0.05$, $^{**}p < 0.01$, n = 4 per group for GLT1 western blotting quantificatinn analysis; n = 4 per group for cell differentiation and proliferation analysis; n = 4 per group for ^{3}H-glutamate uptake assay.

3.3. *Human iPSA transplants showed limited proliferation in vivo and did not form tumors*

A major concern regarding NSC/NPC therapy (particularly with pluripotent cells such as iPS cells) is the potential for uncontrolled proliferation and even tumor formation. To address this concern, we immunostained for the proliferation marker, Ki67, and we examined transplant recipient rat spinal cords for overt tumor formation. With both GFP-hIPSAs (Fig. 4A, C, E) and GLT1-hIPSAs (Fig. 4B, D, F), less than 10% of HuNu$^+$ transplant-derived cells expressed Ki67 at D2 (Fig. 4A–B), W2 (Fig. 4C–D) and W4 (Fig. 4E–F) (quantification shown in Fig. 4G). In addition, we never observed tumor formation in any transplant-recipient animals.

3.4. *Human iPSA transplants showed similar survival and differentiation in the injured mouse cervical spinal cord*

Given the usefulness of the mouse model due to the availability of transgenic tools, we conducted similar characterization of hIPSA fate following transplantation into the mouse spinal cord immediately

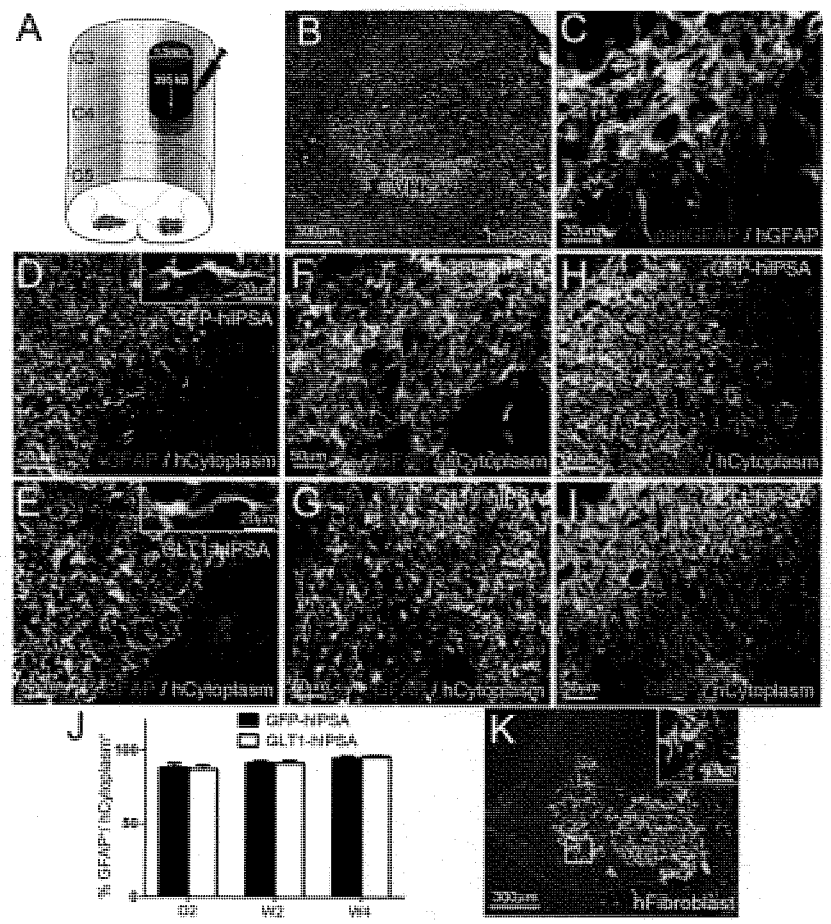

Fig. 2. Human iPSA transplants robustly survived, differentiated into astrocytes and localized to the ventral horn following rat cervical contusion SCI. Immediately following unilateral C4 contusion SCI, we injected GFP-hIPSAs, GLT1-hIPSAs or GFP-hFibro directly into the ventral horn (VH) at locations just rostral and caudal to the contusion site (A). GFP fluorescence indicated that the transplanted hIPSAs were delivered to the ventral horn (B). Double-labeling with pan-GFAP antibody and a human GFAP specific antibody confirmed that all human $GFAP^+$ cells were also pan-$GFAP^+$ (C). Double immunostaining for pan-GFAP and human cytoplasm marker was performed on spinal cord sections from the GFP-hIPSA (D, F, H) and GLT1-hIPSA (E, G, I) groups at day 2 (D–E), week 2 (F–G) and week 4 (H–I) post-injury/transplantation to quantify astrocyte differentiation by transplanted cells (J). We used LV-GFP transduced human fibroblasts (GFP-hFibro) as a non-glial cell control (K, *inset*: high magnification). Results were expressed as means ± SEM. n = 3 per group per time point for transplanted cell differentiation analysis. Red outlines in panels B and K depoote the ventral horn.

following unilateral cervical contusion SCI. Similar to transplantation into the rat SCI model, hIPSAs robustly survived and integrated for at least 4 weeks post-injection. The majority of transplant-derived cells were differentiated $GFAP^+$ astrocytes (Fig. 4H). Control GFP-hIPSAs expressed little GLT1, while overexpression resulted in the majority of transplant-derived astrocytes expressing GLT1 (Fig. 4I). Less than 10%

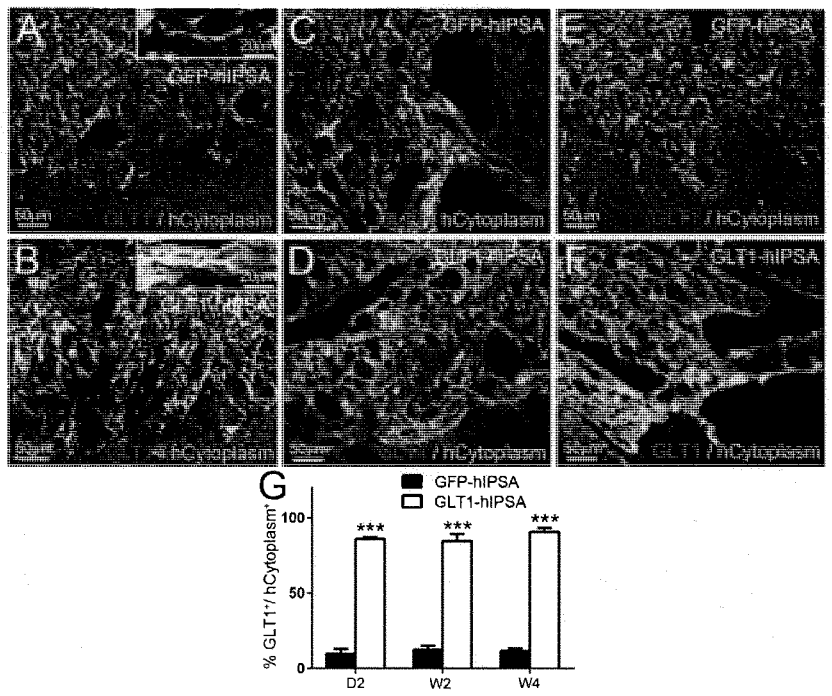

Fig. 3. GLT1-hIPSA transplants expresses GLT1 in the ventral horn following rat cervical contusion SCI. Double immunostaining for GLT1 and human cytoplasm was performed on spinal cord sections from the GFP-hIPSA (A, C, E) and GLT1-hIPSA (B, D, F) groups at day 2 (A–B), week 2 (C–D) and week 4 (E–F) post-injury/transplantation to assess GLT1 expression by transplanted cells *in vivo* (G). Results were expressed as means ± SEM. ***$p < 0.001$. $n = 3$ per group per time point for *in vivo* GLT1 expression analysis.

of transplant-derived cells continued to proliferate at D2, W2 and W4 (Fig. 4J), and again we never observed tumor formation in any mice.

3.5. GLT1 overexpressing hIPSA transplants reduced lesion size following cervical contusion SCI

To test the therapeutic efficacy of hIPSA transplants in the rat unilateral cervical contusion model, we first assessed lesion size. At 4 weeks post-injury, we quantified Cresyl-violet stained transverse sections of the cervical spinal cord surrounding the injury site for the degree of ipsilesional tissue sparing by calculating the percentage of total ipsilateral hemi-cord area comprised of damaged tissue (Fig. 5A). Lesion area (Fig. 5B) and total lesion volume (Fig. 5C) analysis (combined for both white and gray matter) revealed that GLT1-hIPSA transplants significantly reduced lesion size at multiple locations surrounding the epicenter compared to both GFP-hFibro and GFP-hIPSA control transplant groups. We observed this protective effect specifically within 1 mm rostral and caudal of the epicenter where the greatest tissue damage occurred.

3.6. GLT1 overexpressing hIPSA transplants preserved diaphragm innervation by phrenic motor neurons after SCI

We found that GLT1 overexpressing hIPSA transplants significantly preserved morphological innervation at the diaphragm neuromuscular junction (NMJ), the synapse which is critical for functional PMN–diaphragm connectivity. To examine pathological alterations at the diaphragm NMJ, we analyzed hemi-diaphragm muscle ipsilateral to the contusion in rats (Fig. 6A–B). We quantified the percentage of intact NMJs or partially denervated NMJs in the animals from the 3 injection groups at 4 weeks post-injury/transplantation (Wright et al., 2007, 2009; Wright and Son, 2007). For analysis, we divided the hemi-diaphragm into three anatomical regions (ventral, medial and dorsal) (Fig. 6C), as the rostral-caudal axis of the PMN pool within the cervical spinal cord topographically maps onto the ventral-dorsal axis of the diaphragm (Laskowski and Sanes, 1987). At the dorsal region of the hemi-diaphragm, the percentage of intact NMJs in the GLT1-hIPSA transplant group was significantly greater than both control groups, while at the ventral and medial regions of the diaphragm, there were no differences in the percentage of intact NMJs amongst the groups

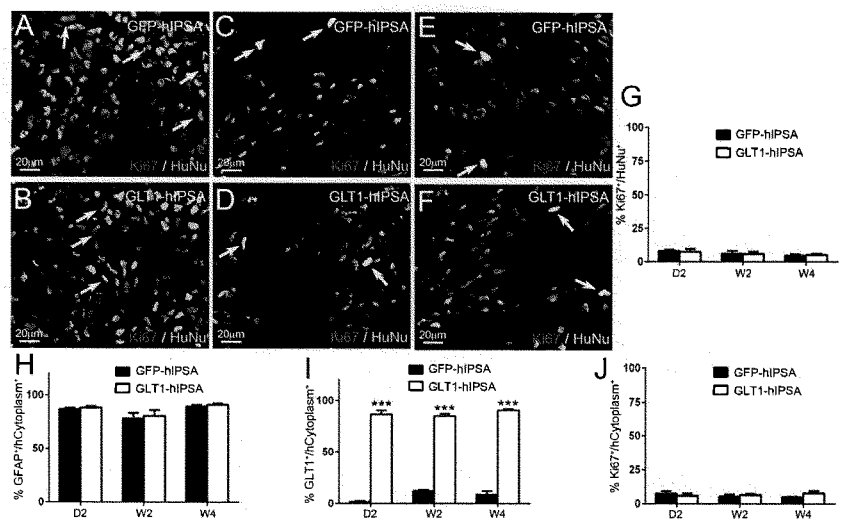

Fig. 4. Transplanted hIPSAs showed limited proliferation and did not form tumors. Double immunostaining for the proliferation marker Ki67 with human nuclei (HuNu) was performed on spinal cord sections from the GFP-hIPSA (A, C, E) and GLT1-hIPSA (B, D, F) groups at D2 (A–B), W2 (C–D) and W4 (E–F) post-transplantation, and quantification results are shown in (G). Tumor formation was never observed. We conducted similar in vivo characterization of hIPSA fate following transplantation into the mouse spinal cord immediately following unilateral cervical contusion SCI. The majority of transplant-derived cells were differentiated $GFAP^+$ astrocytes (H). Control GFP-hIPSAs did not express GLT1, while overexpression resulted in the majority of transplant-derived astrocytes expressing GLT1 (I). Less than 10% of transplant-derived cells continued to proliferate at D2, W2 and W4 (J). Results were expressed as means ± SEM. $^{***}p < 0.001$. n = 3 per group per time point in cell fate analysis.

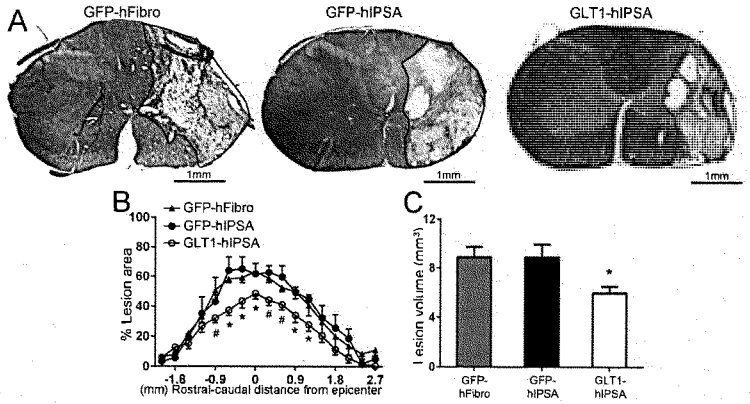

Fig. 5. GLT1 overexpressing hIPSA transplants reduced lesion size following cervical contusion SCI. At 4 weeks post-injury, we quantified Cresyl-violet stained transverse sections of the cervical spinal cord for the degree of ipsilesional tissue sparing by calculating the percentage of total ipsilateral hemi-cord area comprised of damaged tissue (A). Lesion area (B) and total lesion volume (C) analysis (combined for both white and gray matter) revealed that GLT1-hIPSA transplants significantly reduced lesion size at multiple locations surrounding the epicenter compared to both human fibroblast and control GFP-hIPSA transplant groups. Results were expressed as means ± SEM. $\#p < 0.05$, GLT1-hIPSA group *versus* GFP-hIPSA group only; $^*p < 0.05$, GLT1-hIPSA group *versus* both control groups. n = 6 per group for lesion area and volume analysis.

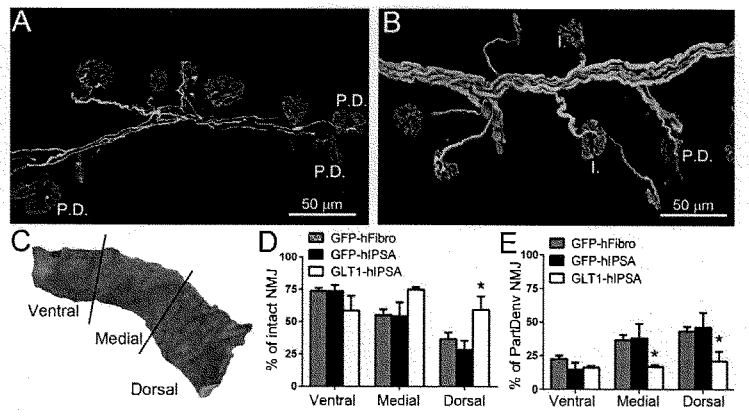

Fig. 6. GLT1 overexpressing hIPSA astrocyte transplants preserved diaphragm innervation by phrenic motor neurons following cervical contusion SCI. To examine pathological alterations at the diaphragm NMJ, hemi-diaphragm muscle ipsilateral to the contusion from the GFP–hFibro (A), GFP–hIPSA and GLT1–hIPSA (B) groups was examined at 4 weeks post-injury/transplantation. Individual NMJs were characterized as: intact (I.) and partially denervated (P.D.). For analysis, the hemi-diaphragm was divided into three anatomical regions (ventral, medial and dorsal) (C). At the dorsal region of the hemi-diaphragm, the percentage of intact NMJs in the GLT1–hIPSA group was significant greater than both control groups (D). GLT1–hIPSA transplants significantly reduced the percentage of partially denervated NMJs in the medial and dorsal hemi-diaphragm regions compared to both control groups (E). Results were expressed as means ± SEM. *$p < 0.05$, GLT1–hIPSA group *versus* both control groups. n = 4–6 per group for NMJ analysis.

(Fig. 6D). GLT1–hIPSA transplants also significantly reduced the percentage of partially denervated NMJs in the medial and dorsal hemi-diaphragm regions compared to both control groups (Fig. 6E).

3.7. GLT1 overexpressing hIPSA transplants preserved diaphragm function following cervical contusion SCI

To determine the efficacy of preserving PMN-diaphragm innervation with respect to respiratory impairment, we characterized the *in vivo* functional effects of transplants on diaphragmatic function in cervical contusion rats. We recorded spontaneous EMG activity, which is indicative of PMN activation of diaphragm muscle due to central drive, at 4 weeks post-injury/transplantation (Fig. 7A). All groups showed reduced amplitude in rhythmic inspiratory EMG bursts associated with muscle contraction compared to uninjured animals (Nicaise et al., 2012). Integrated EMG analysis of this recording shows that the GLT1–hIPSA transplants significantly increased EMG amplitude in the dorsal region of the hemi-diaphragm compared to both control groups (Fig. 7B), again matching the anatomically-specific spinal cord and NMJ histological results. However, we observed no protective effects of GLT1–hIPSA transplants at either the medial or ventral regions, and the control GFP–hIPSA transplants showed no significant effects compared to control hFibroblast injection at all hemi-diaphragm locations (Fig. 7B). There were no significant differences in EMG burst frequency (Fig. 7C) or burst duration (Fig. 7D) amongst the three groups.

Following supramaximal phrenic nerve stimulus, we obtained compound muscle action potentials (CMAP) recordings from the ipsilateral hemi-diaphragm using a surface electrode (Fig. 7E). In all treatment groups, peak CMAP amplitude was significantly reduced compared to uninjured laminectomy only rats, whose CMAP amplitudes are approximately 7 mV (Nicaise et al., 2013). However, CMAP amplitudes in the GLT1–hIPSAtransplant group were significantly increased compared to the two control transplantation groups at weeks 2–4 post-injury (Fig. 7F). With the use of the surface electrode, we are recording from the entire hemi-diaphragm (or at least a significant portion of the muscle), yet we still observed this significant protective effect on overall muscle function, despite the fact that transplants only reduced central degeneration very near to the injury site and correspondingly preserved morphological innervation only in the dorsal hemi-diaphragm.

4. Discussion

The use of iPS cells as a source of mature cell types for therapeutic transplantation in CNS diseases represents an exciting direction in regenerative medicine. However, to date only a small number of studies have assessed the long-term fate and therapeutic efficacy of iPS cell-derived transplants in animal models of SCI.

A number of these studies reported significant therapeutic benefit when NSCs/NPCs derived from either mouse (Tsuji et al., 2010) or human (Fujimoto et al., 2012; Nori et al., 2011; Romanyuk et al., 2014) iPS cells were transplanted into contusion or cavity-type models of rodent SCI, as well as in non-human primate models (Kobayashi et al., 2012). Unlike our current work, these studies did not focus on, or achieve, targeted replacement of astrocytes in the injured spinal cord. In many cases, the cells were delivered in a multipotent NSC-like state and resulted in mixed differentiation into glial phenotypes, including astrocytes, and various neuronal subtypes. While these studies were able to achieve some functional benefit, future work may require more phenotypically targeted strategies, each of which depends on the nature of the SCI pathology (e.g. type of injury and anatomical locations affected) and the specific cell lineages being targeted for replacement. Nevertheless, these studies were able to nicely show promising properties of engrafted cells in the injured spinal cord environment, including synaptic integration into endogenous neuronal circuitry (Fujimoto et al., 2012; Nori et al., 2011). iPS cell-derived NSCs have also shown therapeutic promise in models of other spinal cord diseases such as spinal muscular atrophy (Simone et al., 2014).

A number of these studies with iPS cell transplantation reported a lack of beneficial outcomes in SCI models. Pomeshchik et al. (2014) did not observe functional improvement after transplantation of hIPS

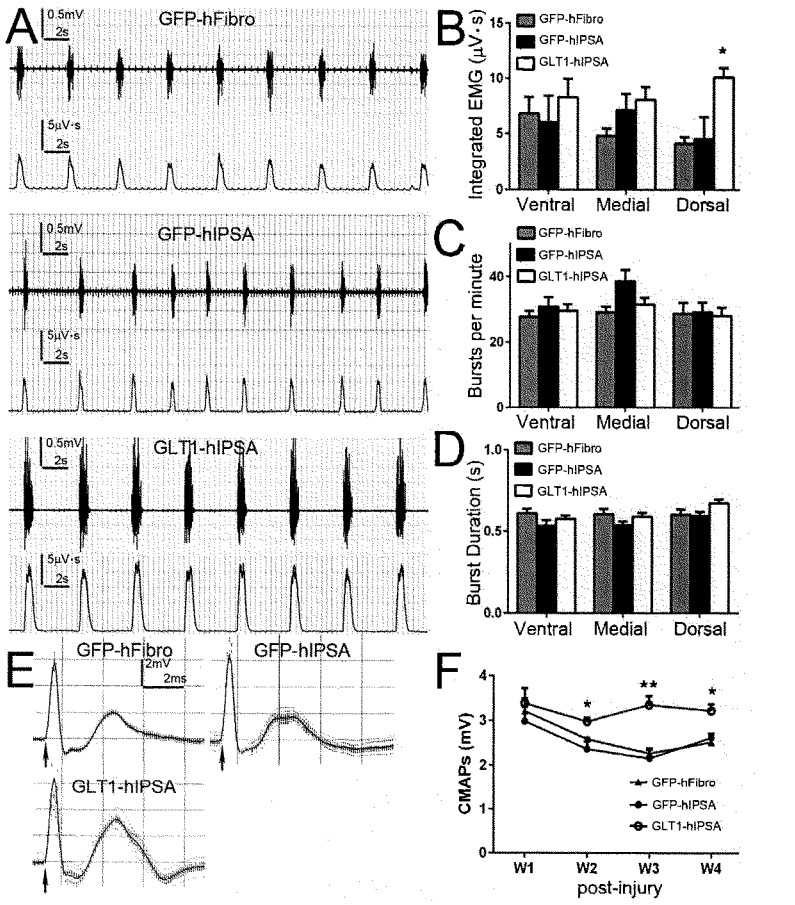

Fig. 7. GLT1 overexpressing hIPSA transplants preserved diaphragm function following cervical contusion SCI. Spontaneous EMG recordings from ipsilateral hemi-diaphram were obtained at 4 weeks post-injury/transplantation (A, *upper*: raw EMG; *lower*: integrated EMG). Integrated EMG amplitude (B), burst frequency (C), and burst duration (D) were analyzed. Following supramaximal phrenic nerve stimulation, we obtained compound muscle action potential (CMAP) recordings from the ipsilateral hemi-diaphragm using a surface electrode (E). CMAP amplitudes at different time points post-injury were analyzed (F). Results were expressed as means ± SEM. $^{*}p < 0.05$, $^{**}p < 0.01$, GLT1-hIPSA group *versus* both control groups. n = 6 per group for EMG and CMAP analysis.

cell-derived NPCs in a contusion SCI model. However, they also did not find long term survival of grafted cells in these mice receiving a tacrolimus immune suppression regimen, unlike the robust and persistent integration that we observed in the present study using an immune suppression protocol consisting of both tacrolimus and rapamycin in mice or cyclosporine in rats. In addition to our work, other groups have reported impressive survival and differentiation of hIPS cells into mature CNS cell types after injection into adult spinal cord of similarly immunosuppressed rodents (Haidet-Phillips et al., 2014; Sareen et al., 2014).

An interesting study from the Horner group (Nutt et al., 2013) reported a lack of therapeutic improvement with transplantation of hIPS cell-derived NPCs in a SCI model, despite impressive graft integration. However, cells were delivered at a chronic time point, which may

represent an environment less amenable to transplant-induced plasticity, while we targeted early neuroprotection in this report.

A recent study from the Steward lab reported that transplantation of a mixed population of glial and neuronal progenitors into a transection model of SCI resulted in ectopic engraftment of large numbers of graft-derived cells in locations such as the central canal, ventricles and pial surface of the spinal cord (Steward et al., 2014), providing a note of caution when using transplantation of any class of NSC/NPC in SCI. This issue is particularly relevant to strategies employing cells derived from pluripotent sources such as ES and iPS cells given the possibility of incomplete and/or inefficient differentiation (Tsuji et al., 2010). In the current study and in our previous work (Lepore et al., 2004, 2005, 2006, 2008b, 2011b; Lepore and Fischer, 2005; Li et al., 2014), we never observed overt tumor formation or extensive migration away from injection sites beyond only a few spinal segments. In the current work, we did note the presence of a small residual population of proliferating transplant-derived cells even out to four weeks post-injection, though we never found any tumor formation. It will be important to assess very long-term time points post-transplantation in future experiments to establish the safety of these and similar types of cells before proceeding to the clinic. Unlike the Steward paper, we did not systematically assess distribution of transplant-derived cells throughout the neuraxis.

Mechanical allodynia (a form of neuropathic pain) was observed when mouse iPSAs were transplanted into a contusion SCI model (Hayashi et al., 2011). In addition to this work, other published studies have similarly reported sensory hypersensitivity in SCI models accompanying transplantation of progenitor-derived astrocytes (Davies et al., 2008; Hofstetter et al., 2005), possibly due to increased neuronal plasticity that is induced by transplantation of immature astrocyte populations (Smith et al., 1986). However, in a large body of work, we and others (Haas et al., 2012; Mitsui et al., 2005; Nutt et al., 2013) have not found such increased sensitivity, including following hIPSA transplantation (Nutt et al., 2013). The discrepancy amongst these studies may be due to heterogeneity in the subtypes of astrocytes being injected (Davies et al., 2008, 2011).

A number of practical issues that are beyond the scope of this discussion will need to be addressed before moving transplantation of iPS cells to the clinic in SCI and other diseases of the nervous system. Specifically with respect to targeting relative early events such as PhMN loss after cervical SCI, autologous derivation of cells will likely not be relevant given that PhMNs are lost within several days post-injury (Nicaise et al., 2013). Instead, cells to be used for transplantation will likely be obtained from banks of immune/HLA-matched cells (Zimmermann et al., 2012). Given the need to extensively test iPS cell lines prior to transplantation into a patient, as well as the costs and time that will be required for generating cells for each individual patient, this approach may actually be practically preferable to autologous derivation (Taylor et al., 2011). As human stem cell lines have shown donor variability in SCI models (Neuhuber et al., 2005), future studies will need to investigate *in vivo* properties and therapeutic efficacy of human iPS cells derived from multiple donors in an attempt to move this approach toward clinical translation.

Similar to our previous work using transplantation of astrocytes derived from rodent glial progenitors (Li et al., 2014), we find that GLT1-overexpresing hIPSAs promote significant preservation of diaphragm function and diaphragm innervation by PhMNs. In both studies, control unmodified transplant-derived astrocytes expressed relatively lower levels of GLT1 in the injured spinal cord, suggesting that the cells respond to the injured environment in a similar manner as host astrocytes that show extensive transporter downregulation. Interestingly, the unmodified hIPSA transplants, despite excellent survival and efficient differentiation, did not promote therapeutic benefit with respect to protection of diaphragmatic respiratory circuitry. These findings suggest that astrocyte replacement alone may insufficient when targeting certain pathological mechanisms (*e.g.* excitotoxocity) but that functional maturation of these astrocytes is necessary, which is not surprising given the diverse, complex and integral roles that astrocytes play in intact CNS function (Pekny and Nilsson, 2005).

We have made interesting observations over the course of a number of studies with respect to therapeutically targeting GLT1 following SCI. We have consistently observed significant GLT1 downregulation in endogenous reactive astrocyte populations in both contusion and crush, as well as both cervical and thoracic, models of SCI (Lepore et al., 2011a, 2011c; Li et al., 2015; Putatunda et al., 2014; Watson et al., 2014). When we selectively increased GLT1 expression in these endogenous astrocytes in the unilateral cervical contusion model using an AAV8 vector, we paradoxically found that secondary degeneration of PhMNs and diaphragm denervation were worsened (Li et al., 2015). This effect was due to compromise in the protective glial scar-forming properties of endogenous astrocytes, which resulted in unexpected expansion of the lesion. In the current study with hIPSAs and in our previous work with rodent-derived glial progenitors (Li et al., 2014), we found that delivery of an exogenous source of astrocytes that expresses high levels of functional GLT1 *via* transplantation (in the exact same cervical contusion model) results in significant preservation of PhMNs and diaphragm function. These findings, as well as other studies that tested the effects of pharmacologically elevating (Olsen et al., 2010) or genetically reducing (Lepore et al., 2011c) GLT1 in SCI, demonstrate that targeting GLT1 is a promising and powerful therapeutic strategy in SCI for targeting neuroprotection and possibly other outcomes of SCI such as neuronal hyperexcitability.

Despite the impressive therapeutic effect achieved in the present study, the degree of PhMN protection and diaphragm function preservation was only partial. In future work, we will need to optimize neuroprotective strategies such as hIPSA transplantation to enhance therapeutic effects, as well as combine these neuroprotective approaches with interventions aimed at promoting plasticity, axonal regrowth and targeted reconnection of the rVRG-PhMN-diaphragm circuit (Alilain et al., 2011). Preserving neural control of diaphragm function involves targeting a complex circuitry that extends beyond just protecting PhMNs (Lane et al., 2009). We focused on preservation of PhMNs centrally in the cervical spinal cord and NMJ innervation peripherally in the diaphragm. Nevertheless, our hIPSA intervention may have also exerted beneficial effects *via* protection of respiratory interneuron populations of the cervical spinal cord and/or descending bulbospinal input to PhMNs from the rVRG. hIPSA transplants may have also resulted in beneficial effects by promoting regrowth/regeneration and/or sprouting of rVRG axons and interneurons, which is possible given the growth-promoting properties of astrocyte transplants after SCI (Davies et al., 2006, 2008, 2011; Haas et al., 2012). However, we only observed therapeutic effects on diaphragm innervation and function with GLT1 overexpressing hIPSAs (but not with control unmodified hIPSAs), suggesting that neuroprotection mediated by increased GLT1 levels and consequent reduction in excitotoxicity was the likely mechanism, even if transplants also promoted some regrowth of respiratory axon populations. We also did not observe differences amongst groups in plasticity at the diaphragm NMJ such as sprouting or reinnervation, further supporting central neuroprotection as the responsible mechanism of therapeutic action.

In conclusion, we report exciting and novel results showing that targeted replacement of astrocyte GLT1 following cervical SCI using hIPSA transplantation significantly preserves diaphragmatic respiratory function. These findings are important for a number of reasons. We demonstrate the therapeutic efficacy and safety of hIPS transplantation in SCI, as well as the benefit of specifically addressing astrocyte dysfunction using this clinically-relevant source of cells. We also show mechanistically that targeting GLT1 using an astrocyte transplant-based approach has profound effects on functional and histopatholoigcal outcomes after SCI. Furthermore, we conducted these studies in a clinically-relevant SCI paradigm that models a large proportion of human disease cases. Excitingly, we find that this intervention results in therapeutic benefit on respiratory function, which has important implications for

SCI patients. Collectively, these studies lay the foundation for translating iPS cell transplantation to the treatment of SCI.

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LETTER

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Kidney organoids from human iPS cells contain multiple lineages and model human nephrogenesis

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The human kidney contains up to 2 million epithelial nephrons responsible for blood filtration. Regenerating the kidney requires the induction of the more than 20 distinct cell types required for excretion and the regulation of pH, and electrolyte and fluid balance. We have previously described the simultaneous induction of progenitors for both collecting duct and nephrons via the directed differentiation of human pluripotent stem cells[1]. Paradoxically, although both are of intermediate mesoderm in origin, collecting duct and nephrons have distinct temporospatial origins. Here we identify the developmental mechanism regulating the preferential induction of collecting duct versus kidney mesenchyme progenitors. Using this knowledge, we have generated kidney organoids that contain nephrons associated with a collecting duct network surrounded by renal interstitium and endothelial cells. Within these organoids, individual nephrons segment into distal and proximal tubules, early loops of Henle, and glomeruli containing podocytes elaborating foot processes and undergoing vascularization. When transcription profiles of kidney organoids were compared to human fetal tissues, they showed highest congruence with first trimester human kidney. Furthermore, the proximal tubules endocytose dextran and differentially apoptose in response to cisplatin, a nephrotoxicant. Such kidney organoids represent powerful models of the human organ for future applications, including nephrotoxicity screening, disease modelling and as a source of cells for therapy.

The mammalian kidney is derived from intermediate mesoderm. Cells from the primitive streak (presomitic mesoderm; PSM) migrate rostrally to form the intermediate mesoderm[2]. The intermediate mesoderm gives rise to both key kidney progenitor populations, the ureteric epithelium and the metanephric mesenchyme, which form the collecting ducts and nephrons, respectively. Several studies have reported the successful differentiation of human pluripotent stem cells (hPSCs) into either ureteric epithelium or metanephric mesenchyme *in vitro*[3–7]. In contrast, we previously reported the simultaneous generation of both ureteric epithelium and metanephric mesenchyme from hPSCs, resulting in the induction of nephrons and collecting ducts[1]. This was paradoxical as it was assumed that the ureteric epithelium arises as a side branch of the mesonephric duct, itself forming from the anterior intermediate mesoderm, while the metanephric mesenchyme is derived from the posterior intermediate mesoderm[5,8]. Retinoic acid (RA) regulates anterior–posterior patterning in organogenesis with rostral RA signalling patterning the somites[9] (Fig. 1e). Conversely, the PSM expresses Cyp26, which attenuates RA signalling in the caudal embryo[10,11]. The PSM is also a strong site of Wnt signalling[12]. In our previous studies, we demonstrated *in vitro* that formation of the intermediate mesoderm required FGF9 or FGF2 (ref. 1). Hence, *in vivo* we assume that the ureteric epithelium forms from early migrating PSM cells exposed to FGF9 and RA soon after the primitive streak stage, while cells late to migrate, and hence exposed to longer Wnt signalling, should give rise to the metanephric mesenchyme[13] (Fig. 1a). To confirm this, we varied the duration of initial Wnt signalling (using CHIR99021, an inhibitor of GSK-3) before addition of FGF9 (Fig. 1b) and monitored markers of the anterior intermediate mesoderm and posterior intermediate mesoderm by quantitative PCR. Shorter periods of CHIR99021 application induced the anterior intermediate mesoderm markers, *LHX1* and *GATA3*, whereas longer periods increased the posterior intermediate mesoderm markers, *HOXD11* and *EYA1*, at day 7. Prolonged expression of the PSM markers, *TBX6* and *T*, after a longer period in the presence of CHIR99021 suggested a delay in FGF9-induced fate commitment (Fig. 1c), as predicted. Immunofluorescence analysis showed that a longer (or shorter) period with CHIR99021 induced less (more) anterior intermediate mesoderm but more (less) posterior intermediate mesoderm, as indicated by GATA3 and HOXD11, respectively, at day 7 of differentiation (Fig. 1d). These observations persisted after 18 days of culture, with dominant ureteric epithelium induction ($GATA3^+PAX2^+ECAD^+$) after fewer days in the presence of CHIR99021 and preferential induction of metanephric mesenchyme ($PAX2^+ECAD^-$) and its derivatives ($PAX2^+ECAD^+$) with more days in the presence of CHIR99021 (Extended Data Fig. 1a). Further, we investigated whether RA signalling also controls anterior–posterior fate patterning of the intermediate mesoderm using RA or an RA receptor antagonist, AGN193109, together with FGF9 (Fig. 1e, f). RA promoted ureteric epithelium induction, whereas AGN193109 inhibited ureteric epithelium but enhanced induction of the metanephric mesenchyme lineage (Fig. 1g and Extended Data Fig. 1b).

These results increase our understanding of embryogenesis as well as providing a method by which to modulate the relative induction of each of the two intermediate mesoderm-derived progenitor populations essential for kidney formation. As a result, we modified our existing kidney differentiation process to increase the proportion of metanephric mesenchyme formed, increase the time in 3D culture and actively trigger nephron formation. This optimized approach was applied to either human embryonic stem (ES) cells or human induced pluripotent stem (iPS) cells and involved an initial 4 days of CHIR99021, which resulted in the induction of both the ureteric epithelium and the metanephric mesenchyme in monolayer culture (Extended Data Fig. 2), followed by 3 days of FGF9 before transfer to organoid culture (Fig. 2a). The resulting aggregates were cultured for up to 20 days, during which time they spontaneously formed complex kidney organoids (Fig. 2b). During normal mouse kidney development, nephron formation from the metanephric mesenchyme is initiated in response to Wnt9b secreted from the ureteric epithelium. In the mouse, ectopic nephron formation can be triggered via the addition of canonical Wnt agonists[14]. Indeed, maximal nephron number per organoid required a pulse of CHIR99021 for one hour after forming a pellet (Fig. 2a and Extended Data Fig. 3a). In addition, the continued presence of FGF9 after this CHIR99021 pulse was essential

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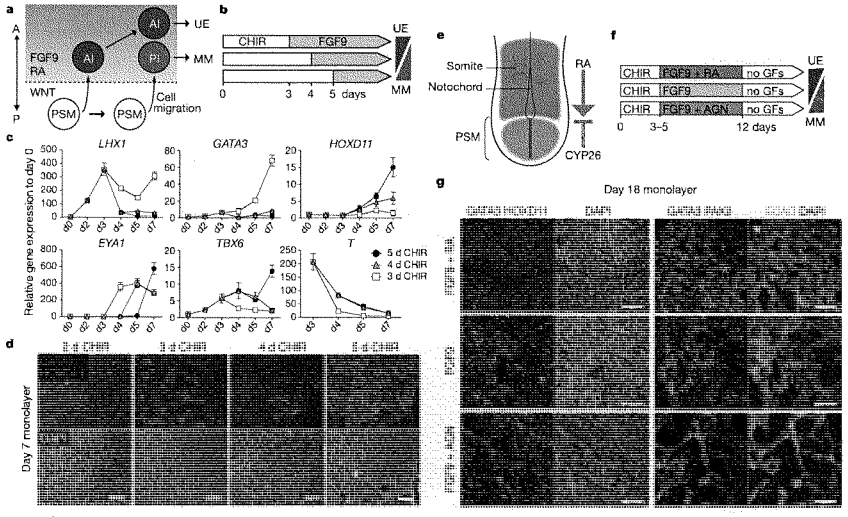

Figure 1 | Selective induction of either the collecting duct or kidney mesenchyme lineage. **a**, Schematic illustrating the mechanism of anterior–posterior (A–P) patterning of the intermediate mesoderm in the embryogenesis[13]. The timing of PSM cell migration determines the timing of the exposure to FGF9 and RA, resulting in fate selection between anterior intermediate mesoderm and posterior intermediate mesoderm. AI, anterior intermediate mesoderm; MM, metanephric mesenchyme; PI, posterior intermediate mesoderm; PSM, presomitic mesoderm; UE, ureteric epithelium. **b**, Schematic of three experimental timelines. CHIR, CHIR99021. **c**, Time course quantitative PCR of an initial 7 days (d) of the differentiation from the above timings. Experiments were conducted using monolayer culture condition (mean ± s.d., $n = 3$ independent experiments). **d**, Immunofluorescence at day 7 of differentiation with the AI marker, GATA3, and the PI marker, HOXD11. Scale bars, 100 μm. Experimental replicates, 3. **e**, Schematic illustrating RA signalling after the primitive streak stage. An RA-metabolizing enzyme, CYP26, is expressed in the PSM region to shield PSM cells from RA signalling. **f**, Schematic of three experimental timelines. RA or AGN193109 (AGN) were added with FGF9 after CHIR99021, followed by growth factor withdrawal (no GFs). Experiments were conducted with monolayer culture condition. **g**, Immunofluorescence at day 18 of differentiation from 3 days of CHIR99021 followed by ± RA/AGN. AGN inhibited the AI specification of early migrating cells, causing posteriorization. At day 18, GATA3 and HOXD11 mark the UE and the MM, respectively (left panels). $GATA3^+PAX2^+ECAD^+$ cells represent the UE whereas $GATA3^-PAX2^+$ cells do the MM ($ECAD^-$) and its derivatives ($ECAD^+$) (right panels). Experimental replicates, 3. Scale bars, 100 μm.

for nephrogenesis, suggesting an additional role for FGF signalling after Wnt-mediated nephron induction (Extended Data Fig. 3b). Within each organoid, the nephrons appropriately segmented into 4 components, including the collecting duct ($GATA3^+ECAD^+$), the early distal tubule ($GATA3^-LTL^-ECAD^+$), early proximal tubule (LTL^+ECAD^-) and the glomerulus ($WT1^+$) (Fig. 2c, d). Moreover, kidney organoids showed complex morphogenetic patterning with collecting duct trees forming at the bottom of the organoid, connecting to distal and proximal tubules in the middle, with the glomeruli at the top of each organoid (Fig. 2e and Supplementary Videos 1 and 2). This patterning mimics the tissue organization observed *in vivo* where glomeruli arise in the cortex whereas the collecting ducts radiate through the organ from the middle. Here again, the relative level of collecting duct versus nephron within individual organoids could be varied with the timing of the initial CHIR99021-to-FGF9 switch (Extended Data Fig. 4a, b). Next, we performed RNA sequencing of whole kidney organoids at day 0, 3, 11 and 18 after aggregation and 3D culture. Across this time course we observed a temporal loss of nephron progenitor gene expression but an increase in markers of multiple nephron segments, including the podocytes, proximal and distal tubules (Extended Data Fig. 5 and Supplementary Table 2). Transcriptional profiling was performed and compared using an unbiased method with human fetal transcriptional data sets from 21 human fetal organs/tissues from the first and/or second trimester of pregnancy[15]. This analysis clustered kidney organoids at d11 and d18 of culture with first trimester human fetal kidney (Fig. 2f, g and Extended Data Fig. 6). At the earlier culture time points (day 0 and 3), organoids more closely matched the fetal gonad, an embryologically closely related tissue also derived from the intermediate mesoderm.

In a kidney, the epithelial cell types (nephron and collecting duct) are surrounded by a renal interstitium (stroma) within which there is a vascular network. As well as forming the metanephric mesenchyme, the intermediate mesoderm gives rise to stromal and vascular progenitors (Fig. 3a)[16,17]. We examined kidney organoids for evidence of additional cell types and evidence of functional maturation. Collecting ducts could be distinguished based on co-expression of PAX2, GATA3 and ECAD (Fig. 3b). At d11, nephron epithelia showed proximal (LTL^+ECAD^-) and distal (LTL^-ECAD^+) elements (Fig. 3c). By day 18, proximal tubules matured to co-express LTL with ECAD, with cubilin evident on the apical surface (Fig. 3d, e). Transmission electron microscopy (TEM) showed distinct epithelial subtypes; cells with few short microvilli surrounding an open lumen characteristic of collecting duct/distal tubule (Fig. 3k) and typical proximal tubular epithelium displaying an apical brush border with tight junctions (Fig. 3l). By day 18, loops of Henle ($UMOD^+$) began to form (Fig. 3f). By day 11, $WT1^+NPHS1^+$ early glomeruli[18] comprising a Bowman's capsule

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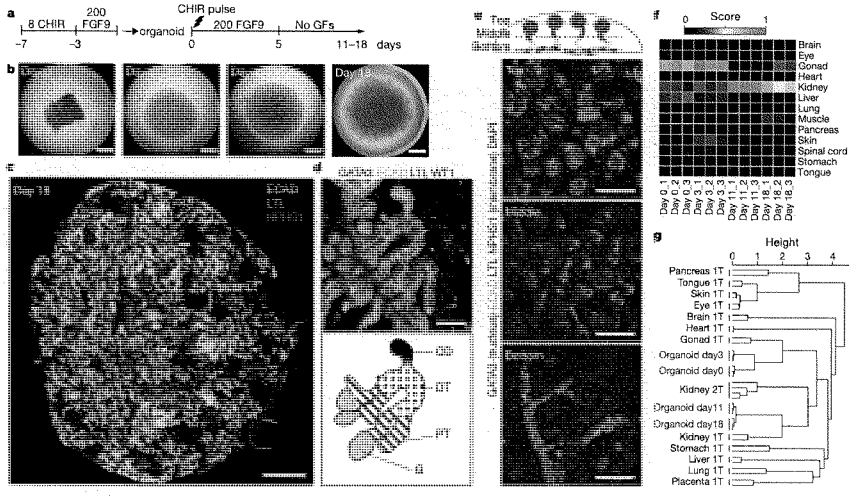

Figure 2 | Generating a kidney organoid equivalent to the human fetal kidney *in vitro*. **a**, Schematic of the differentiation protocol from hPSCs. 8 CHIR, 8 μM CHIR99021; 200 FGF9, 200 ng ml^{-1} FGF9. **b**, Global bright field observations of self-organizing kidney organoids across a time series. The success rate of organoid differentiation was 94.2% (138 organoids, 5 experiments). Scale bars, 1 mm. **c**, Tile scan immunofluorescence of a whole kidney organoid displaying structural complexity. Scale bar, 1 mm. **d**, High-power immunofluorescence microscopy showing a nephron segmented into 4 compartments, including the collecting duct (CD, GATA3$^+$ECAD$^+$), distal tubule (DT, GATA3$^-$ECAD$^+$LTL$^-$), proximal tubule (PT, ECAD$^-$LTL$^+$) and the glomerulus (G, WT1$^+$). Scale bar, 100 μm. **e**, Confocal microscopy generating serial *z*-stack images from the bottom to the top of a day 11 kidney organoid (Supplementary Videos 1 and 2). Schematic illustrates the position of different structures within an organoid. Top, middle and bottom images are representative images taken through the organoids at the position indicated in **e**. Each segment of the nephron is marked (or coloured in schematic) as described below: collecting ducts, GATA3$^+$ECAD$^+$ (green dots in yellow); distal tubules, ECAD$^+$ (yellow); proximal tubules, LTL$^+$ (red); glomeruli, NPHS1 (green circles). Scale bars, 100 μm. **f**, Heat map visualizing the relative transcriptional identity (score from 0 to 1 determined using the KeyGene algorithm[33]) of kidney organoids to 13 human fetal tissues. RNA-seq was performed on whole kidney organoids from 4 time points (day 0, 3, 11 and 18 after aggregation) with 3 individual organoids from 1 experiment per time point (see Supplementary Table 2). **g**, A dendrogram showing the hierarchical clustering of day 0, 3, 11 and 18 kidney organoids with human fetal organs from both first trimester and second trimester, based on 85 key genes (Supplementary Table 3) previously defined[33]. This clearly shows a close match with trimester 1 fetal kidney from day 11 and 18 of culture.

with central podocyte formation was seen connected to proximal tubules (Fig. 3g). Kidney organoids also developed a CD31$^+$ KDR$^+$SOX17$^+$ endothelial network with lumen formation (Fig. 3h and Extended Data Fig. 7a, b, c). TEM showed the presence of primary and secondary foot processes characteristic of podocytes (Fig. 3m). In a developing kidney, renal interstitium differentiates into pericytes and mesangial cells[19]. As expected, kidney organoids contained PDGFRA$^+$ perivascular cells that lie along KDR$^+$ endothelia and PDGFRA$^+$ early mesangial cells invaginating the glomeruli, as observed in human fetal kidney[20] (Extended Data Fig. 8a, b). Early avascular glomeruli contained basement membrane, as indicated by laminin staining and TEM, and showed attaching foot processes on the basement membrane (Extended Data Fig. 8c, d). In some instances, glomeruli showed evidence of endothelial invasion (Fig. 3i and Supplementary Videos 3 and 4), a feature never observed in explanted embryonic mouse kidneys[21]. Finally, nephrons were surrounded by MEIS1$^+$ renal interstitial cells[22], some of which were also FOXD1$^+$ (Fig. 3j and Extended Data Fig. 8e), suggesting the presence of cortical (FOXD1$^+$MEIS1$^+$) and medullary (FOXD1$^-$MEIS1$^+$) stroma. Hence, all anticipated kidney components form, pattern and begin to mature within these hPSC-derived kidney organoids. Consistent with these observations were the transcriptional changes across time in culture, with a gradual reduction in the nephrogenic mesenchyme and ureteric tip markers followed by the upregulation of genes specific to podocyte, proximal tubule, distal tubule and loop of Henle[23].(Extended Data Fig. 5).

The utility of stem-cell derived kidney organoids for disease modelling or drug screening will be dependent upon the functional maturation of the nephrons within these organoids. To test this, we focused on the proximal tubules, a nephron segment that has important roles in solute, vitamin, hormone and amino acids reabsorption. The capacity of cubilin-mediated proximal tubule specific endocytosis was demonstrated by the selective uptake of dextran–Alexa488 from the media by the LTL$^+$ tubules after 24 h of exposure (Fig. 4a and Extended Data Fig. 9a, b). The proximal tubules represent a particular target for nephrotoxicity due to the expression of multidrug resistance (such as ABCB1, ABCG2) and anion and cation transporters (such as the SLC22 gene family)[24]. Cisplatin is one such nephrotoxicant that induces caspase-mediated acute apoptosis of proximal tubular cells in the kidney[25,26]. We treated kidney organoids with 0, 5 and 20 μM cisplatin for 24 h before examining cleaved-CASP3 antibody staining (Extended Data Fig. 9c). While control organoids showed occasional apoptotic interstitial cells, both 5 μM and 20 μM cisplatin induced specific acute apoptosis in mature proximal tubular cells (LTL$^+$ECAD$^+$), whereas immature cells (LTL$^+$ECAD$^-$) did not undergo apoptosis (Fig. 4b, c).

In summary, this study demonstrates that by carefully balancing anterior–posterior patterning of intermediate mesoderm with small

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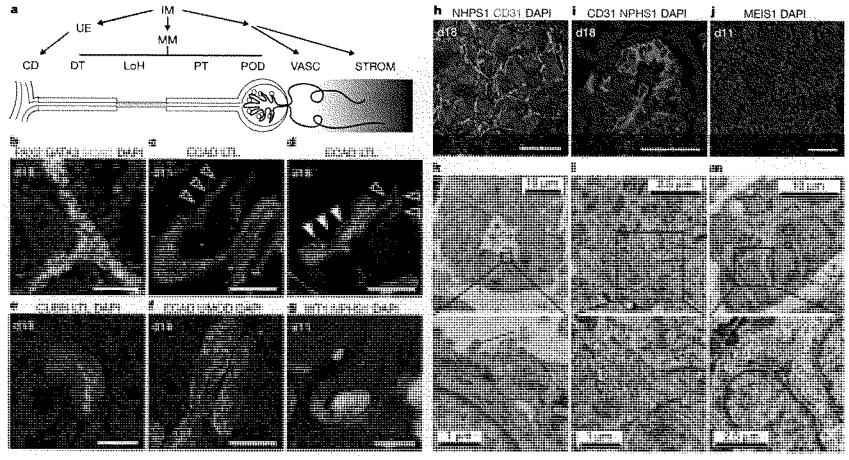

Figure 3 | Kidney organoids contain differentiating nephrons, stroma and vasculature with progressive maturation with time in culture. **a**, Schematic illustrating the developmental pathway from intermediate mesoderm (IM) to each cellular component of the kidney. CD, collecting ducts; DT, distal tubules; LoH, loops of Henle; PT, proximal tubules; POD, podocytes; VASC, vasculature; STROM, renal interstitium. **b**–**j**, Immunofluorescence of kidney organoids at either day 11 or 18. **b**, Collectiog ducts marked by PAX2, GATA3 and ECAD. Scale bar, 50 μm. **c**, **d**, Early proximal tubules of LTL^+ECAD^- at day 11 (black arrowheads). LTL^+ECAD^+ maturing proximal tubules appear by day 18 (white arrowheads). Scale bars, 100 μm. **e**, Proximal tubules express cubilin (CUBN). Scale bar, 50 μm. **f**, Loops of Henle marked by UMOD and ECAD. Scale bar, 50 μm. **g**, A developing glomerulus with podocytes marked by WT1 and NPHS1. Scale bar, 50 μm. **h**, $CD31^+$ endothelia within the renal interstitium Scale bar, 200 μm. **i**, Evidence of endothelial invasion into glomeruli at day 18 of culture. Scale bar, 50 μm. **j**, The kidney interstitium marked by MEIS1. Scale bar, 100 μm. **k**–**m**, Transmission electron microscopy of kidney organoids **k**, A putative distal tubule with relatively sparse short microvilli (m) and tight junctions (tj). **l**, A putative proximal tubule with a lumen filled with extensive closely packed microvilli characteristic of the brush border (bb). **m**, Podocytes (p with characteristic large nuclei and primary (pf) and secondary foot (sf) processes. Data are representative from a minimum of 3 independent experiments.

molecules it is possible to direct human pluripotent stem cells to form a complex multicellular kidney organoid that comprises fully segmented nephrons surrounded by endothelia and renal interstitium and is transcriptionally similar to a human fetal kidney. As such, these will improve our understanding of human kidney development. Each kidney organoid reaches a substantial size with more than 500 nephrons per organoid, a number equivalent to a mouse kidney at 14.5 days post-coitum[27]. While there is room for further improvement with regard to

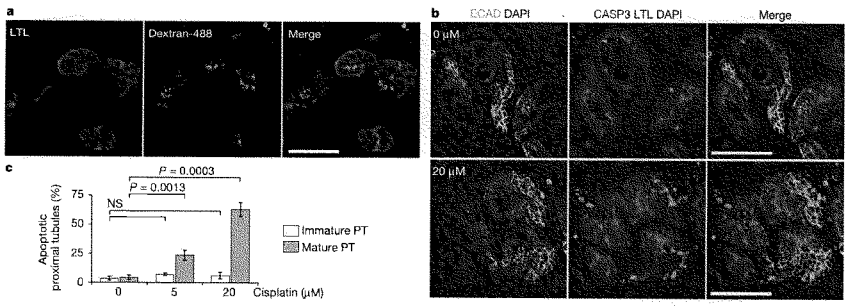

Figure 4 | Functional maturation of the proximal tubule. **a**, Dextran uptake assay showing endocytic ability of LTL^+ tubules. Scale bar, 50 μm. **b**, Treating kidney organoids with 20 μM cisplatin caused apoptosis in LTL^+ECAD^+ proximal tubular cells. Apoptotic cells were detected by cleaved caspase 3 antibody-staining (CASP3). Scale bars, 100 μm. **c**, Quantification of the number of apoptotic tubules showing mature proximal tubules-specific apoptosis by a nephrotoxicant, cisplatin. In response to 5 μM and 20 μM cisplatin, LTL^+ECAD^+ mature proximal tubules (PT) underwent apoptosis dose-dependently. In contrast, LTL^+ECAD^- immature PT did not respond to cisplatin. *P* values were calculated by independent *t*-test (mean ± s.e.m., $n = 5$ independent experiments); NS, not significant.

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tubular functional maturity, glomerular vascularisation and a contiguous collecting duct epithelium with a single exit path for urine, the tissue complexity and degree of organoid functionalization observed here supports their use to screen drugs for toxicity, modelling genetic kidney disease or act as a source of specific kidney cell types for cellular therapy.

Online Content Methods, along with any additional Extended Data display items and Source Data, are available in the online version of the paper; references unique to these sections appear only in the online paper.

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Supplementary Information is available in the online version of the paper.

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Author Contributions M.T. and M.H.L. planned the project, designed experiments, analysed and interpreted data and wrote the manuscript. M.T. performed experiments. P.X.E. maintained hES/iPS cells. P.X.E. and H.S.C. performed experiments under the supervision of M.T and M.H.L.; B.M. generated organoids for TEM. G.J.B. analysed bioinformatic data. C.F. performed TEM. R.G.P. captured and interpreted TEM images. E.J.W. provided the iPS cell line and advised on general iPS cell quality control. M.S.R. and S.M.C.d.S.L. developed NGS analytical tools and analysed data for RNA-seq profiling.

Author Information The RNA-seq data have been deposited in the Gene Expression Omnibus (http://www.ncbi.nlm.nih.gov/geo/) under accession number GSE70101. Reprints and permissions information is available at www.nature.com/reprints. The authors declare competing financial interests: details are available in the online version of the paper. Readers are welcome to comment on the online version of the paper. Correspondence and requests for materials should be addressed to M.T. (minoru.takasato@mcri.edu.au) or M.H.L. (melissa.little@mcri.edu.au).

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METHODS

No statistical methods were used to predetermine sample size, the experiments were not randomized and the investigators were not blinded to allocation during experiments and outcome assessment.

Cell culture and differentiation. All experiments presented used the previously described wild-type human iPS cell line CRL1502 (clone C32) generated using episomal reprogramming[28]. Undifferentiated human iPS cells were maintained on the mouse embryonic fibroblasts (MEFs) (Millipore) as a feeder layer with human ES cell (hES) medium as described previously[1]. Cells were authenticated and tested for the mycoplasma infection[28]. Human iPS cells were plated on a Matrigel-coated (Millipore) culture dish and cultured in MEF-conditioned hES medium (MEF-CM) until reaching 60–100% confluence. Then, cells were again plated on a Matrigel-coated at 5,000 cells per cm^2 in MEF-CM. Next day, cells reached 40–50% of confluence, cells were treated with 8 μM CHIR99021 in APEL basal medium (STEMCELL Technologies) supplemented with Antibiotic-Antimycotic (Life Technologies) for 2–5 days, followed by FGF9 (200 ng ml^{-1}) and heparin (1 μg ml^{-1}) for another 5–2 days, with changing medium every second day. At day 7, cells were collected and dissociated into single cells using trypsin or TrypLE select (Life Technologies). Cells (0.5×10^6) were spun down at ×400*g* for 2 min to form a pellet and then transferred onto a Transwell 0.4 μm pore polyester membrane (CLS3450 Corning). Pellets were treated with 5 μM CHIR99021 in APEL for 1 h, and then cultured with FGF9 (200 ng ml^{-1}) and heparin (1 μg ml^{-1}) for 5 days, followed by another 6–13 days in APEL basal medium, with changing medium three times a week. Culture medium should not overflow over the membrane. For the differentiation in monolayer cultures, cells after CHIR99021 induction were treated by FGF9 (200 ng ml^{-1}) and heparin (1 μg ml^{-1}) for 10 days, followed by APEL basal medium for another 6 days. In some experiments, RA (0.1 μM) or AGN193109 (5 μM) were added to FGF9 medium. A step-by step protocol describing kidney organoid generation can be found at Protocol Exchange[29].

Immunocytochemistry. For monolayer cells, antibody staining was performed as described previously[1]. For the kidney organoid, organoids were fixed with 2% paraformaldehyde in PBS for 20 min at 4 °C followed by 3 times wash with PBS. Then organoids were blocked with 10% donkey serum, 0.3% Triton X/PBS for 2–3 h at room temperature and incubated with primary antibodies overnight at 4 °C. After 5 times washing with 0.1% Triton X/PBS, secondary antibodies were incubated for 4 h at room temperature. The following antibodies and dilutions were used: rabbit anti-PAX2 (1:300, 71-6,000, Zymed Laboratories), goat anti-SIX1 (1:300, sc-9709, Santa Cruz Biotechnology), rabbit anti-SIX2 (1:300, 11562-1-AP, Proteintech), mouse anti-ECAD (1:300, 610181, BD Biosciences), rabbit anti-WT1 (1:100, sc-192, Santa Cruz Biotechnology), mouse anti-HOXD11 (1:300, SAB1403944, Sigma-Aldrich), goat anti-GATA3 (1:300, AF2605, R&D Systems), rabbit anti-JAG1 (1:300, ab7771, Abcam), goat anti-cubilin (1:150, sc-20607, Santa Cruz Biotechnology), sheep anti-NPHS1 (1:300, AF4269, R&D Systems), LTL-biotin-conjugated (1:300, B-1325, Vector Laboratories), DBA-biotin-conjugated (1:300, B-1035, Vector Laboratories), mouse anti-KRT8 (1:300, TROMA, DSHB), mouse anti-CD31 (1:300, 555444, BD Pharmingen), rabbit anti-KDR (1:300, 2479, Cell Signaling Technology), goat anti-SOX17 (1:300, AF1924, R&D Systems), mouse anti-PDGFRA (1:200, 556001, BD Pharmingen), rabbit anti-Laminin (1:300, L9393, Sigma-Aldrich), rabbit anti-UMOD (1:300, BT-590, Biomedical Technologies), mouse anti-MEIS1 (1:300, ATM39795, activemotif), goat anti-FOXD1 (1:200, sc-47585, Santa Cruz Biotechnology) and rabbit anti-cleaved-CASP3 (1:300, 9661, Cell Signaling Technology). Images were taken using a Nikon Ti-U microscope or a Zeiss LSM 780 confocal microscope. All immunofluorescence analyses were successfully repeated more than three times and representative images are shown.

Electron microscopy. Organoids were processed for electron microscopy using a method as follows. A solutiou of 5% glutaraldehyde in 2 × PBS was added directly to tbe organoid culture dish in equal volume to the growth medium and placed under vacuum for 5 min. The organoid was reduced in size by cuttiog into small blocks (~2 × 2 mm), and irradiated in fresh fixative 2.5%, again under vacuum, for 6 min, in a Pelco Biowave (Ted Pella In, Redding, CA) at 80 W power. Samples were then washed 4 × 2 min in 0.1 M cacodylate buffer. Samples were then immersed in a solution containing potassium ferricyanide (3%) and osmium tetroxide (2%) in 0.1 M cacodylate buffer for 30 min at room temperature. Following 6 × 3 min washes in distilled water the tissue blocks were then incubated in a filtered solution containing thiocarbohydrazide (1%) for 30 min at room temperature. After subsequent washing in distilled water (6 × 2 min) samples were incubated in an aqueous solution of osmium tetroxide (2%) for 30 min, then in distilled water (6 × 2 min) and incubated in 1% aqueous uranyl acetate for 30 min at 4 °C. After further distilled water washes (2 × 2 min) a freshly prepared filtered solution of 0.06% lead nitrate in aspartic acid (pH 5.5) warmed to 60 °C was added to the dish and further incubated for 20 min at 60 °C before rinsing in distilled water (6 × 3 min) at room temperature. Tissue blocks were dehydrated twice in each ethanol solution of 30%, 50%, 70%, 90% and absolute ethanol for 40 s at 250 W in the Pelco Biowave. Epon LX112 resin was used for embedding the tissue with infiltration at 25%, 50%, and 75% resin:absolute ethanol in the Pelco Biowave under vacuum at 250 W for 3 min and finishing with 100% resin (twice), before the final embedding/blocking and curing at 60 °C for 12 h.

qRT–PCR analysis. Total RNA was extracted from cells using Purelink RNA mini kit (Life Technologies) and cDNA was synthesized from >100 ng total RNA using Super Script III reverse transcriptase (Life Technologies). qRT–PCR analyses were performed with GoTaq qPCR Master Mix (Promega) by Roche LightCycler 96 real-time PCR machine. All absolute data were first normalized to GAPDH and then normalized to control samples ($\Delta\Delta C_t$ method). The sequences of primers used for qRT–PCR are as listed in Supplementary Table 1.

Next generation RNA sequencing and comparative analysis using KeyGenes. Sequencing was performed using the Illumina NextSeq500 (NextSeq control software v1.2/Real Time Analysis v2.1) platform. The library pool was diluted and denatured according to the standard NextSeq500 protocol and sequencing was carried out to generate single-end 76 bp reads using a 75 cycle NextSeq500 High Output reagent Kit (Catalog FC-404-1005). Reads were mapped against the reference human genome (hg19) using STAR[30], and read counts for each gene in the UCSC annotation were generated using htseq-count in the HTSeq python package (http://www-huber.embl.de/users/anders/HTSeq/doc/index.html). The number of uniquely mapped reads ranged from 18,810,634 to 36,706,805 per sample. Normalized read counts were calculated using the DESeq2 package[31].

KeyGenes was used to generate the identity scores of day 0, 3, 11 and 18 kidney organoids to different first trimester human organs, including the kidneys (GSE66302)[15]. The dendrogram showing the hierarchical clustering of day 0, 3, 11 and 18 kidney organoids and 21 human fetal organs from first and second trimester (GSE66302) was based on the Pearson correlation of the expression levels of 85 classifier genes as determined by KeyGenes (http://www.keygenes.nl) (Supplementary Table 3). The classifier genes were calculated by KeyGenes using the top 500 most differentially expressed genes of the human fetal data without including the extraembryonic tissues from that data set.

Functional analysis for proximal tubules. For dextran uptake assay, organoids at day 17 were cultured with 10 μg ml^{-1} of 10,000 MW dextran Alexa488-conjugated (D-22910, Life Technologies) for 24 h. Organoids were fixed and stained by LTL without permeabilization. For nephrotoxicity assays, organoids at day 17 were cultured with 0, 5, 20 or 100 μM cisplatin (Sigma-Aldrich) for 24 h. The ratio of apoptotic proximal tubules to total proximal tubules was manually counted using ImageJ in 2 or 3 representative fields per experiment. In total, $n = 5$ independent experiments. Images were taken using Zeiss LSM 780 confocal microscope.

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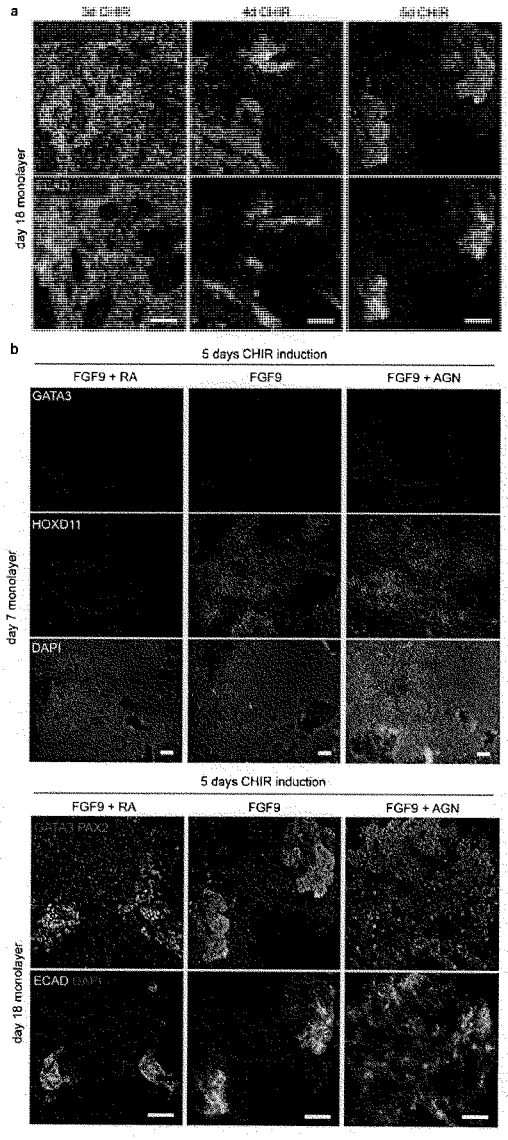

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Extended Data Figure 1 | Antero-posterior intermediate mesoderm specification is regulated by the timing of FGF9 exposure and the presence of RA signalling. a, Immunofluorescence at day 18 of monolayer differentiation from cultures exposed to different timing of FGF9 addition (after 2, 3, 4 and 5 days of CHIR99021). The ureteric epithelium is represented by $GATA3^+PAX2^+ECAD^+$ cells. The metanephric mesenchyme and its derivatives are marked by $PAX2^+GATA3^-ECAD^-$ (metanephric mesenchyme) and $PAX2^+GATA3^-ECAD^+$ (nephrons), respectively. Scale bars, 100 μm. **b**, Immunofluorescence at day 7 and 18 of monolayer differentiation using 5 days of CHIR99021 followed by RA or AGN193109 (AGN) on top of FGF9. RA reduced the specification of posterior intermediate mesoderm, as indicated by the reduction of HOXD11 at day 7 (top panel). This resulted in less metanephric mesenchyme but some ureteric epithelium by RA at day 18 (bottom panel). Scale bars, 100 μm.

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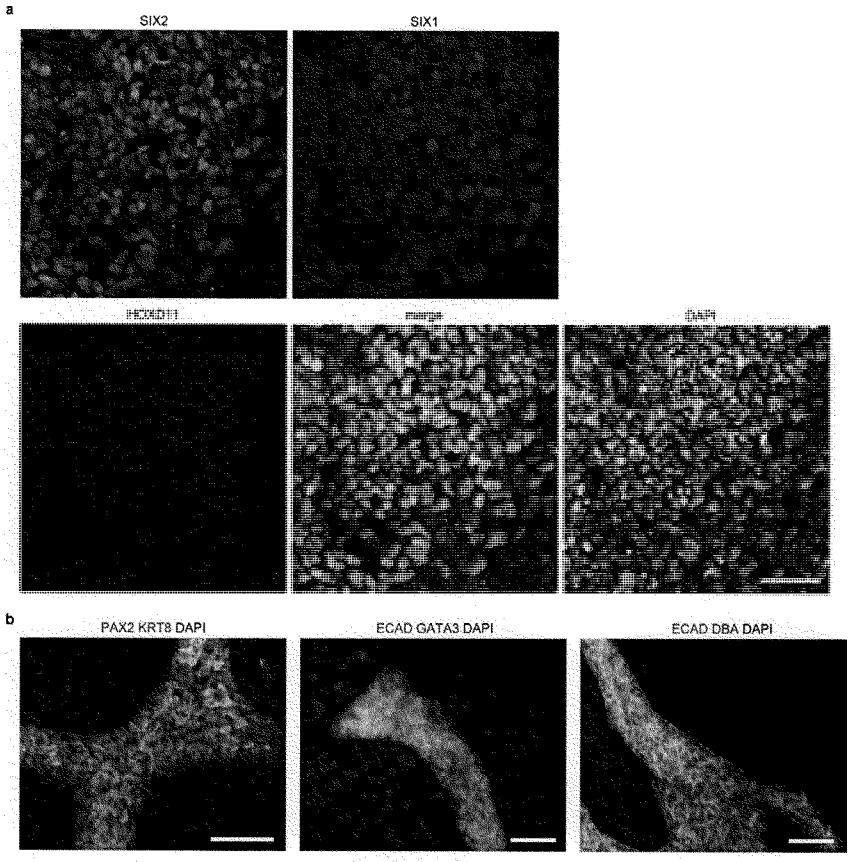

Extended Data Figure 2 | Induction of both kidney progenitors at the same time. a, b, Immunofluorescence at day 18 of the monolayer differentiation using the 4 days CHIR99021 before FGF9 protocol. The metanephric mesenchyme is marked by $SIX2^+SIX1^+HOXD11^+$ cells (**a**). $GATA3^+$ $PAX2^+ECAD^+KRT8^+$ cells representing the ureteric epithelium were also induced (**b**). Scale bars, 50 μm.

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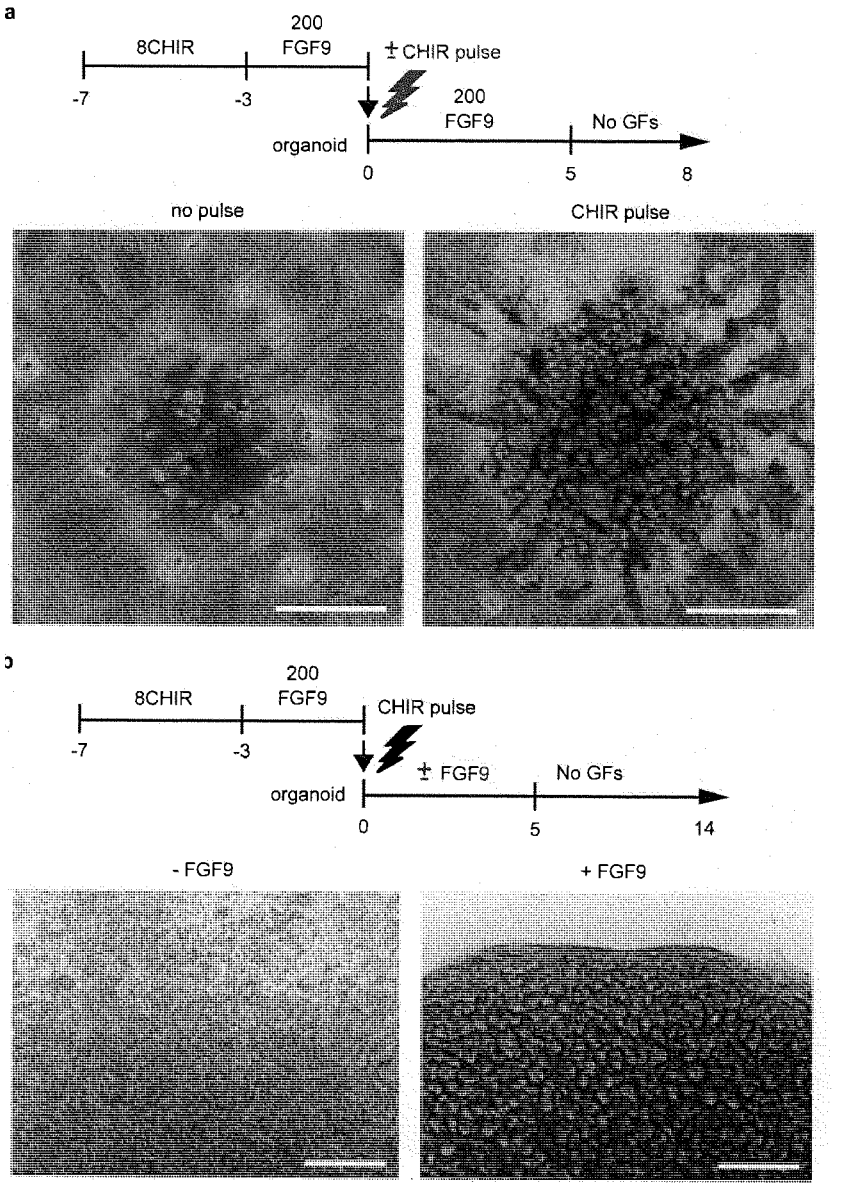

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Extended Data Figure 3 | Regulation of nephrogenesis in the kidney organoid. **a**, Stimulating organoids with 5 μM CHIR99021 for 1 h immediately after aggregation promoted nephrogenesis (CHIR pulse), whereas only limited numbers of nephrogenesis events happened without CHIR99021 (no pulse). Scale bars, 1 mm. **b**, Without the addition of FGF9 after this CHIR99021 pulse, organoids did not initiate nephrogenesis (−FGF9). Scale bars, 200 μm.

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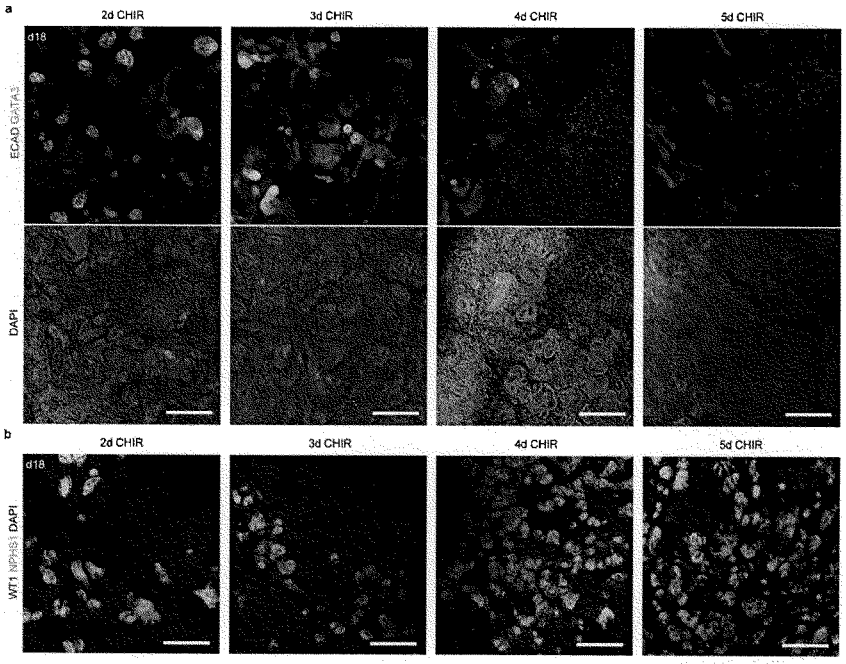

Extended Data Figure 4 | The timing of FGF9 exposure affects the ratio of collecting duct to nephron in the kidney organoid. a, b, Immunofluorescence of kidney organoids at day 18 after-aggregation after exposure to different timings of initial FGF9 exposure (2, 3, 4 and 5 days of CHIR99021 pre-FGF9), demonstrating the regulation of collecting duct/nephron ratio by varying this timing. $GATA3^{+}ECAD^{+}$ cells represent the collecting duct (**a**), whereas $WT1^{+}NPHS1^{+}$ cells mark podocytes of the glomerulus (**b**). Scale bars, 200 μm.

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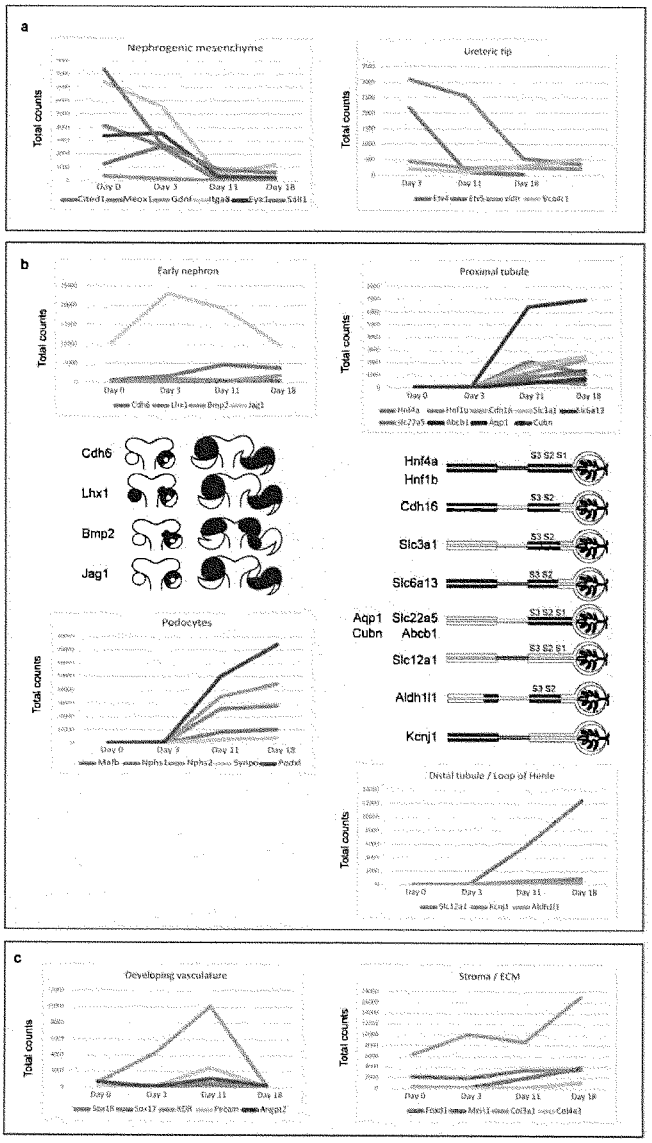

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Extended Data Figure 5 | Changes of gene expression during development of the kidney organoid. a–c, Graphs showing expression changes of selected marker genes at 4 time points (day 0, 3, 11 and 18) of the kidney organoid culture. *y* axis represents the count of detection for each gene in an RNA sequencing analysis. Markers of the nephron progenitor (cap mesenchyme) and collecting duct progenitor (ureteric tip) were peaked by day 3 then dropped (a). Markers of early nephron increased by day 3, while those of mature nephron components (Proximal and distal tubule and Podocytes) started after day 3. Illustrations show expression regions (blue coloured) of each selected gene in the developing kidney (b). Markers of endothelial and renal interstitial cells were also increased by day 11 (c).

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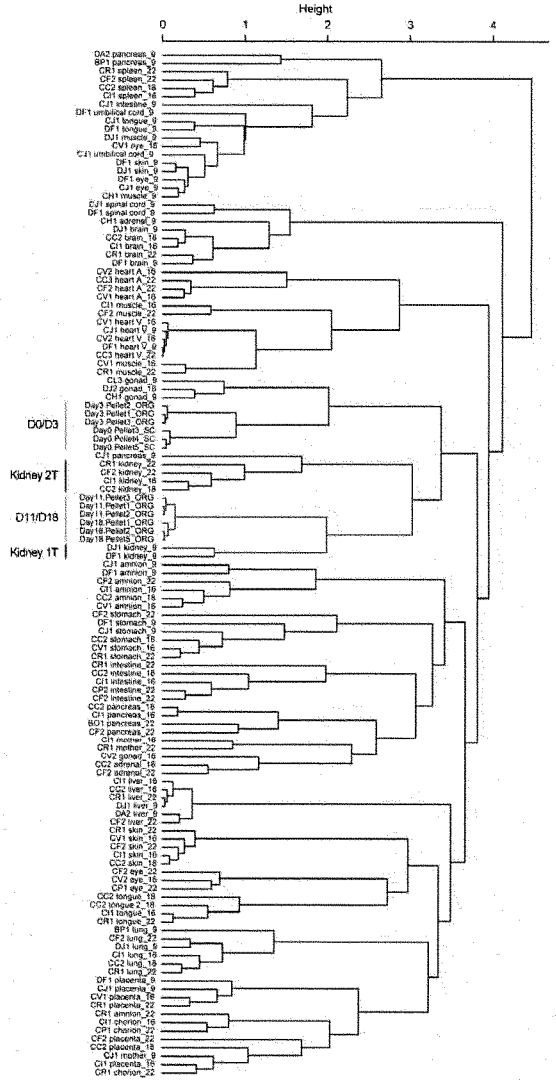
RESEARCH LETTER



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Extended Data Figure 6 | Transcriptional similarity of the kidney organoid to human fetal organs. Dendrogram showing the hierarchical clustering of day 0, 3, 11 and 18 differentiation experiments and 21 human fetal organs from first and second trimester (Gene Expression Omnibus accession number GSE66302)[15]. Sample name is composed of individual ID followed by an organ name and gestation week. For instance, 'DJ1 kidney_9' represents a kidney at ninth week gestation from individual ID: DJ1. Day 0 and 3 kidney organoids cluster with gonad, in agreement with the common origin of both gonad and kidney from the intermediate mesoderm. Day 11 and 18 kidney organoids show strongest similarity to trimester 1 human kidney. The classifier genes used for this analysis are detailed in Supplementary Table 3.

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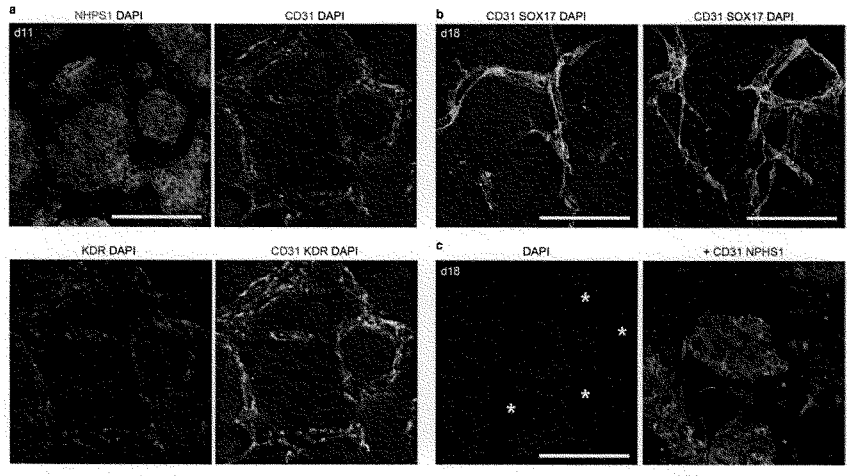

Extended Data Figure 7 | Evidence of endothelial cells in the kidney organoid. **a**, Immunofluorescence of day 11 kidney organoids showing the presence of $CD31^+KDR^+$ endothelial cells surrounding $NPHS1^+$ glomeruli. Scale bar, 100 μm. **b**, Two representative images demonstrating the expression of another endothelium marker SOX17 in $CD31^+$ endothelial cells. Scale bars, 100 μm. **c**, Immunofluorescence of day 18 kidney organoids displaying endothelia with lumen formation, as indicated by asterisks. This image also shows the endothelial invasion into a glomerulus. Scale bar, 100 μm.

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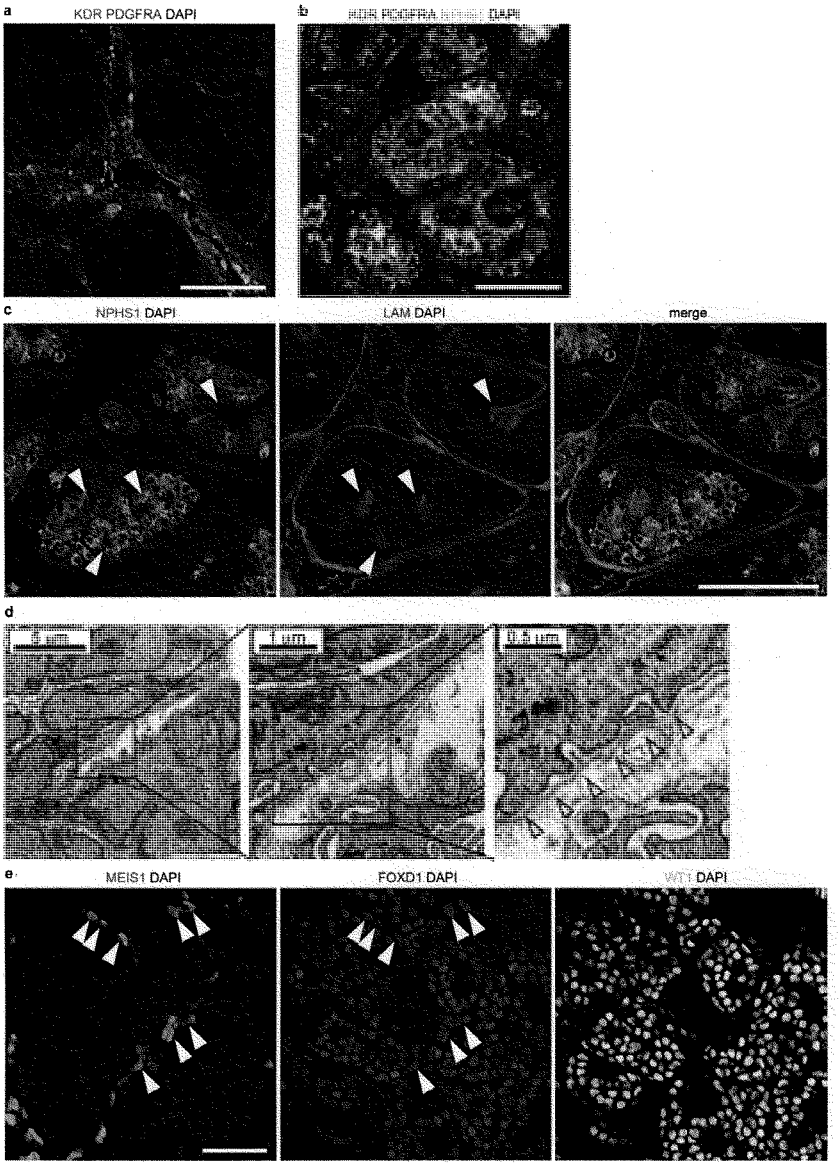

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Extended Data Figure 8 | Characterization of non-epithelial structures in the kidney organoid. All images were taken from day 18 kidney organoids. **a**, PDGFRA$^+$ pericytic cells attaching on KDR$^+$ vessels. Scale bar, 50 μm. **b**, Some glomeruli contained PDGFRA$^+$ cells likely to represent early mesangial cells[19]. Scale bar, 50 μm. **c**, Laminin staining (LAM) demonstrates the presence of basement membrane in glomerulus structures (white arrowheads). Scale bar, 100 μm. **d**, TEM images of avascular glomeruli showing early podocytes surrounding a basement membrane (yellow arrowheads) and exhibiting foot processes on the basement membrane. **e**, Immunofluorescence showing FOXD1 expression in podocytes (WT1$^+$FOXD1$^+$)[18] and a subpopulation of MEIS1$^+$ interstitium (white arrowheads). This is suggestive of the presence of both cortical stroma (FOXD1$^+$MEIS1$^+$) and medullary stroma (FOXD1$^-$MEIS1$^+$). Scale bar, 100 μm.

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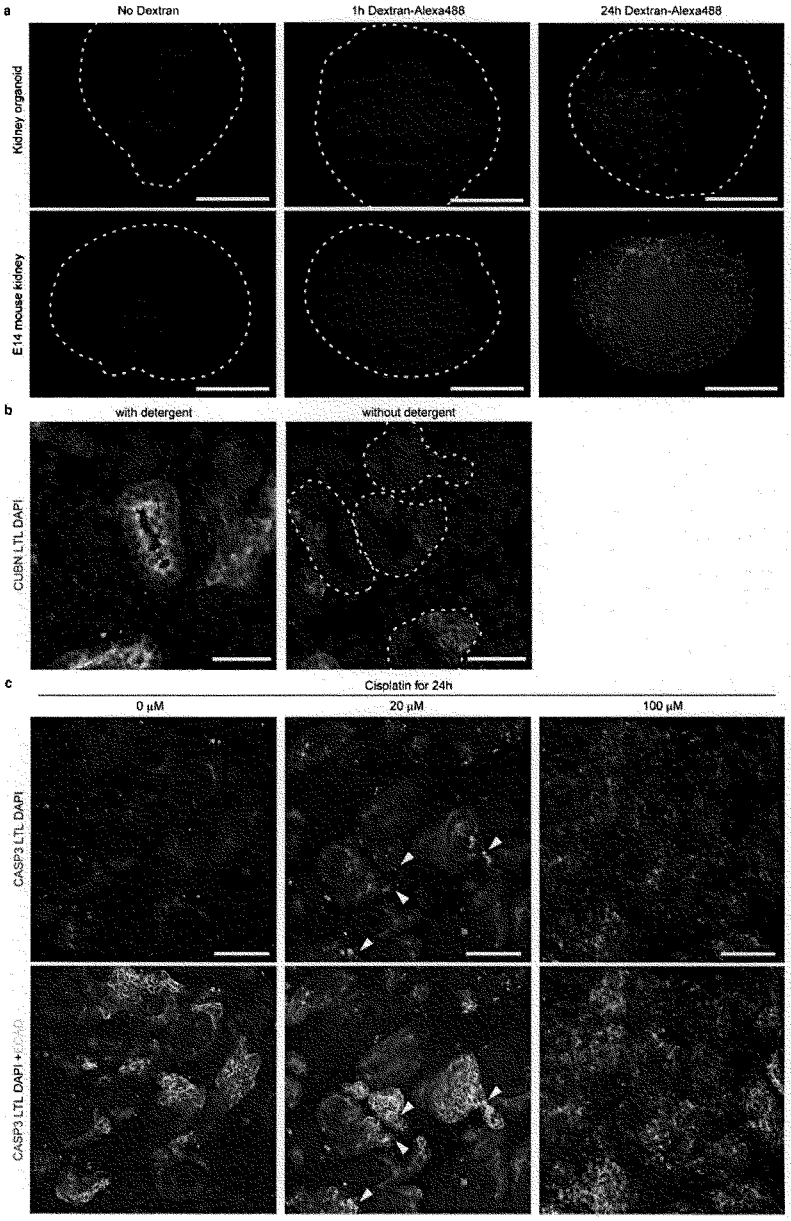

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Extended Data Figure 9 | Functional assay of proximal tubule maturation within kidney organoids. **a**, Fluorescent microscopy showing the dextran uptake in both the kidney organoids and E14 mouse embryonic kidneys organ culture after 24 h presence of dextran–Alexa488 (10 $\mu g\,ml^{-1}$) in the culture medium (24 h dextran–Alexa488). 1 h incubation was insufficient for either organoids or mouse kidney explants to uptake dextran from the culture media (1 h dextran–Alexa488). No background signals were detected in a control without dextran (no dextran). Dashed line circles the organoids and kidneys. Scale bars, 1 mm. **b**, Endocytosis mediator cubilin (CUBN) was present on apical surface of the proximal tubules in kidney organoids (left panel). The same staining without detergent during the process showed the complete absence of CUBN staining on apical surface (right panel), demonstrating that the tubules within the organoids are intact. This explains the requirement for a 24 h incubation with dextran before evidence of apical uptake. Dashed line circles LTL^+ proximal tubules. Scale bars, 50 μm. **c**, Low power immunofluorescence microscopy of day 18 kidney organoids after being treated by cisplatin for 24 h. No apoptosis was observed in proximal tubules in the absence of cisplatin (0 μM, left panel). LTL^+ECAD^+ proximal tubular cell-specific apoptosis was observed only in response to either 5 μM (not shown) or 20 μM cisplatin (arrowheads in middle panel). Global cell death was observed after culture in 100 μM cisplatin (right panel). Scale bars, 100 μm.

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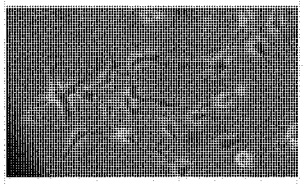

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Growth Properties: adherent

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Additional Information

Product Use	Tempo's iAstro™ cells are intended for basic research and drug development use only. It is not a product for human testing or diagnostics.

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Fetal Pain

A Systematic Multidisciplinary Review of the Evidence

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Context Proposed federal legislation would require physicians to inform women seeking abortions at 20 or more weeks after fertilization that the fetus feels pain and to offer anesthesia administered directly to the fetus. This article examines whether a fetus feels pain and if so, whether safe and effective techniques exist for providing direct fetal anesthesia or analgesia in the context of therapeutic procedures or abortion.

Evidence Acquisition Systematic search of PubMed for English-language articles focusing on human studies related to fetal pain, anesthesia, and analgesia. Included articles studied fetuses of less than 30 weeks' gestational age or specifically addressed fetal pain perception or nociception. Articles were reviewed for additional references. The search was performed without date limitations and was current as of June 6, 2005.

Evidence Synthesis Pain perception requires conscious recognition or awareness of a noxious stimulus. Neither withdrawal reflexes nor hormonal stress responses to invasive procedures prove the existence of fetal pain, because they can be elicited by nonpainful stimuli and occur without conscious cortical processing. Fetal awareness of noxious stimuli requires functional thalamocortical connections. Thalamocortical fibers begin appearing between 23 to 30 weeks' gestational age, while electroencephalography suggests the capacity for functional pain perception in preterm neonates probably does not exist before 29 or 30 weeks. For fetal surgery, women may receive general anesthesia and/or analgesics intended for placental transfer, and parenteral opioids may be administered to the fetus under direct or sonographic visualization. In these circumstances, administration of anesthesia and analgesia serves purposes unrelated to reduction of fetal pain, including inhibition of fetal movement, prevention of fetal hormonal stress responses, and induction of uterine atony.

Conclusions Evidence regarding the capacity for fetal pain is limited but indicates that fetal perception of pain is unlikely before the third trimester. Little or no evidence addresses the effectiveness of direct fetal anesthetic or analgesic techniques. Similarly, limited or no data exist on the safety of such techniques for pregnant women in the context of abortion. Anesthetic techniques currently used during fetal surgery are not directly applicable to abortion procedures.

JAMA. 2005;294:947-954 www.jama.com

OVER THE LAST SEVERAL years, many states, including California, Kentucky, Minnesota, Montana, New York, Oregon, and Virginia, have considered legislation requiring physicians to inform women seeking abortions that the fetus feels pain and to offer fetal anesthesia. This year, Arkansas and Georgia enacted such statutes.[1,2] Currently, Congress is considering legislation requiring physicians to inform women seeking abortions 20 or more weeks after fertilization (ie, 22 weeks' gestational age) that the fetus has "physical structures necessary to experience pain," as evidenced by "draw[ing] away from surgical instruments." The physician must also offer anesthesia or analgesia "administered directly" to the fetus. Physicians who do not comply may be subject to substantial fines, license revocation, and civil suits for punitive damages.[3]

Although this legislation would not affect most US abortions because only 1.4% are performed at or after 21 weeks' gestational age,[4] this legislation raises important scientific, clinical, ethical, and policy issues. When does a fetus have the functional capacity to feel pain? If that capacity exists, what forms of anesthesia or analgesia are safe and effective for treating fetal pain? As a first step in answering these questions, we reviewed the literature on fetal pain and fetal anesthesia and analgesia.

CME available online at www.jama.com

EVIDENCE ACQUISITION

English-language articles involving human participants were searched using PubMed for (1) *fetal pain* (16 articles), *fetal anesthesia* (6 articles), and *fetal analgesia* (3 articles); (2) *fetus* and (*anesthesia or analgesia*) (1239 articles); (3) Medical Subject Headings (MeSH) *an-*

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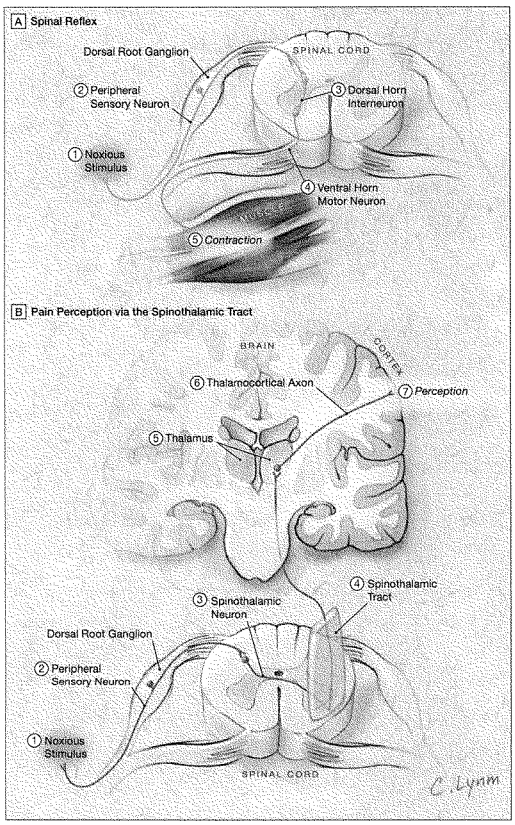
Figure. Spinal Reflex and Pain Perception Pathways



A, Reflex responses to noxious stimuli occur early in development, before thalamocortical circuits are functional; noxious stimuli trigger reflex movement without cortical involvement. Activated by a noxious stimulus (1), a peripheral sensory neuron (2) synapses on a dorsal horn interneuron (3) that in turn synapses on a ventral horn motor neuron (4), leading to reflex muscle contraction and limb withdrawal (5). B, Later in development, noxious stimuli (1) activate peripheral sensory neurons (2) that synapse on spinothalamic tract neurons (3), the axons of which extend up the spinal cord as the spinothalamic tract (4) to synapse on neurons of the thalamus (5). From here, thalamocortical axons synapse on cortical neurons, resulting in the conscious perception of pain.

algesics/administration and dosage and *fetus* (44 articles); (4) MeSH *anesthesia/administration and dosage* and *fetus* (0 articles); (5) (*neurodevelopment or development or anatomy*) and (*fetus or fetal*) and (*pain or nociception or noxious*) (306 articles); (6) (*thalamocortical or thalamus or cortex*) and (*fetus or fetal*) and (*pain or nociception or noxious*) (13 articles); (7) (*electroencephalog* or EEG or evoked potential*) and (*fetus or fetal or premature neonate or premature infant or preterm neonate or preterm infant*) and (*pain or nociception or noxious or conscious**) (7 articles); (8) *fetal* and *pain* and (*response or assessment or facial expression*) (112 articles); and (9) *facial expression* and (*fetus or fetal*) or ([*neonate or neonatal or infant*] *and* [*premature or preterm*]) and (*pain or nociception or noxious*) (360 articles). The search was performed without date limitations and was current as of June 6, 2005. From these search results, we excluded articles that did not study fetuses of less than 30 weeks' gestational age or that did not specifically address fetal pain perception or nociception. With a focus on topics addressed by earlier review articles on fetal pain, anesthesia, and analgesia, articles were reviewed for additional references.

EVIDENCE SYNTHESIS

What Is Pain?

Pain is a subjective sensory and emotional experience that requires the presence of consciousness to permit recognition of a stimulus as unpleasant.[5-7] Although pain is commonly associated with physical noxious stimuli, such as when one suffers a wound, pain is fundamentally a psychological construct that may exist even in the absence of physical stimuli, as seen in phantom limb pain.[5,7] The psychological nature of pain also distinguishes it from nociception, which involves physical activation of nociceptive pathways without the subjective emotional experience of pain.[5,8] For example, nociception without pain exists below the level of a spinal cord lesion, where reflex withdrawal from a noxious stimulus occurs without conscious perception of pain (FIGURE, A).[5]

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Table. Anatomical and Functional Development of Nociception and Pain Perception Pathways

Anatomical/ Functional Characteristic	Description	Gestational Age, wk	Source
Peripheral cutaneous sensory receptors	Perioral cutaneous sensory receptors	7.5	Humphrey,[13] 1964
	Palmar cutaneous sensory receptors	10-10.5	
	Abdominal cutaneous sensory receptors	15	
Spinal cord	Spinal reflex arc in response to nonnoxious stimuli	8	Okado and Kojima,[14] 1984
	Neurons for nociception in dorsal root ganglion	19	Konstantinidou et al,[15] 1995
Thalamic afferents	Thalamic afferents reach subplate zone	20-22	Kostovic and Rakic,[16] 1990 Hevner,[17] 2000
	Thalamic afferents reach cortical plate	23-24	Kostovic and Rakic,[18] 1984 Kostovic and Goldman-Rakic,[19] 1983
Cortical function*	Somatosensory evoked potentials with distinct, constant components	29	Klimach and Cooke,[20] 1988 Hrbek et al,[21] 1973
	First electrocardiographic pattern denoting both wakefulness and active sleep	30	Clancy et al,[22] 2003 Torres and Anderson,[23] 1985

*Earliest evidence of functional thalamocortical connections required for conscious perception of pain.

Because pain is a psychological construct with emotional content, the experience of pain is modulated by changing emotional input and may need to be learned through life experience.[7,9,10] Regardless of whether the emotional content of pain is acquired, the psychological nature of pain presupposes the presence of functional thalamocortical circuitry required for conscious perception, as discussed below.

Fetal Capacity for Pain

Neuroanatomy and Development. Nociception may be characterized by reflex movement in response to a noxious stimulus, without cortical involvement or conscious pain perception. Nociception involves peripheral sensory receptors whose afferent fibers synapse in the spinal cord on interneurons, which synapse on motor neurons that also reside in the spinal cord. These motor neurons trigger muscle contraction, causing limb flexion away from a stimulus (Figure, A).[11]

In contrast, pain perception requires cortical recognition of the stimulus as unpleasant. Peripheral sensory receptor afferents synapse on spinal cord neurons, the axons of which project to the thalamus, which sends afferents to the cerebral cortex (Figure, B),[11] activating any number of cortical regions.[12] Sensory receptors and spinal cord synapses required for nociception develop earlier than the thalamocortical pathways required for conscious perception of pain (TABLE).

No human studies have directly examined the development of thalamocortical circuits associated with pain perception. The developmental age at which thalamic pain fibers reach the cortex has been inferred from studies of other thalamocortical circuits, which may or may not develop at the same time as thalamic fibers mediating cortical perception of pain.

These histological neurodevelopment studies typically describe fetal maturity in terms of developmental age, representing the number of weeks postovulation or postfertilization. Clinicians regularly use gestational age, representing weeks from the first day of the woman's last menstrual period. When referring to a fetus at the same point in development, the gestational age is approximately 2 weeks greater than the developmental age.

A histological study of the visual pathway in 8 human fetuses, each at a different developmental age, concluded that thalamic projections reach the visual cortex at 21 to 25 weeks' developmental age (approximately 23-27 weeks' gestational age), based on results from a fetus of 24 weeks' developmental age (26 weeks' gestational age).[18] A similar 7-fetus study found thalamic afferents reached the auditory cortical plate at 24 to 26 weeks' developmental age, with 1 specimen showing initial cortical plate penetration at 22 weeks' developmental age (24 weeks' gestational age).[24]

In a study of 8 human fetuses, mediodorsal thalamic afferents were first observed in the cortical plate at 22 weeks' developmental age (24 weeks' gestational age).[19] While connections between mediodorsal afferents and the anterior cingulate cortex[25] may be relevant to pain perception,[12,26] this study examined mediodorsal afferents to unspecified regions of the frontal cortex,[19] which serves numerous functions unrelated to pain perception.[19,27]

Another histological study of 12 specimens found that afferents from unspecified thalamic regions reached the developing prefrontal cortex in 1 preterm neonate of 27 weeks' developmental age, concluding that thalamic fibers begin entering the cortex between 26 and 28 weeks' developmental age (28 and 30 weeks' gestational age).[28] A different study found that thalamic afferents had not reached the somatosensory cortical plate by 22 weeks' developmental age (24 weeks' gestational age). By 24 weeks' developmental age (26 weeks' gestational age), the density of cortical plate synapses increased, although these were not necessarily from thalamic afferents.[16] Based on these studies, direct thalamocortical fibers that are not specific for pain begin to emerge between 21 and 28 weeks' developmental age (23 and 30 weeks' gestational age).

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However, others have proposed that thalamocortical connections could also be established indirectly if thalamic afferents were to synapse on subplate neurons, which could synapse on cortical plate neurons.[29] The subplate is a transient fetal structure 1 layer deep to the cortical plate and serves as a "waiting compartment" for various afferents, including thalamic afferents, en route to the cortical plate.[16,29,30] The subplate recedes after 30 weeks' developmental age,[16,29] while the cortical plate matures into the 6 layers of the cerebral cortex.[28] In contrast to direct thalamocortical fibers, which are not visible until almost the third trimester, thalamic afferents begin to reach the somatosensory subplate at 18 weeks' developmental age (20 weeks' gestational age)[16] and the visual subplate at 20 to 22 weeks' gestational age.[17] These afferents appear morphologically mature enough to synapse with subplate neurons,[31] although no human study has shown that functional synapses exist between thalamic afferents and subplate neurons. Subplate neurons may synapse with cortical plate neurons and direct the growth of thalamic afferents to their final synaptic targets in the cortical plate.[29] Despite this developmental role, no human study has shown that synapses between subplate and cortical plate neurons convey information about pain perception from the thalamus to the developing cortex.

Electroencephalography. The histological presence of thalamocortical fibers is insufficient to establish capacity for pain perception. These anatomical structures must also be functional. Although no electroencephalographic "pain pattern" exists, electroencephalography may be one way of assessing general cortical function because electroencephalograms (EEGs) measure summated synaptic potentials from cortical neurons. However, EEG activity alone does not prove functionality, because neonates with anencephaly who lack functional neural tissue above the brainstem may still have EEG activity.[32]

Normal EEG patterns have been characterized for neonates as young as 24 weeks' postconceptional age (PCA) (ie, the gestational age plus number of weeks postpartum).[22] Electroencephalographic activity is normally asynchronous between the hemispheres and mostly discontinuous at less than 27 weeks' PCA,[23,33,34] becoming mostly continuous around 34 weeks' PCA.[23,34] Interhemispheric synchrony increases around 29 to 30 weeks' PCA, then declines, then increases again, reaching almost complete synchrony by term.[22,33] Given these baseline differences between neonatal and adult EEGs, patterns associated with impaired consciousness in adults[33,35] are inapplicable to the analysis of neonatal EEGs.

Some investigators contend that EEG patterns denoting wakefulness indicate when consciousness is first possible.[5,36] Wakefulness is a state of arousal mediated by the brainstem and thalamus in communication with the cortex.[5,22] In preterm neonates, the earliest EEG pattern representing wakefulness appears around 30 weeks' PCA.[22,23] However, wakefulness alone is insufficient to establish consciousness, as unconscious patients in a persistent vegetative state may also have wakeful EEGs.[5,36]

Somatosensory evoked potentials (SEPs) may also provide evidence of pain processing in the somatosensory cortex, although they are not used clinically to test pain pathways. SEPs test the dorsal column tract of the spinal cord, which transmits visceral pain sensation to the somatosensory cortex via the thalamus.[12] SEPs with distinct and constant N1 components of normal peak latency are present at 29 weeks' PCA, indicating that thalamic connections with the somatosensory cortex are functional at that time.[20,21]

Behavioral Studies. Although widely used to assess pain in neonates, withdrawal reflexes and facial movements do not necessarily represent conscious perception of pain. Full-term neonates exhibit a "cutaneous withdrawal reflex" that is activated at a threshold much lower than that which would produce discomfort in a child or adult.[37] This threshold increases with PCA, suggesting that the capacity of the neonate to distinguish between noxious and nonnoxious stimuli is maturing.[37] Furthermore, flexion withdrawal from tactile stimuli is a noncortical spinal reflex exhibited by infants with anencephaly[38] and by individuals in a persistent vegetative state[39] who lack cortical function.

Behavioral studies have also identified a distinct set of neonatal facial movements present during invasive procedures such as heel lancing but absent during noninvasive procedures.[40-46] These facial movements, which are similar to those of adults experiencing pain,[47,48] were evident in neonates at 28 to 30 weeks' PCA but not at 25 to 27 weeks' PCA.[40] Facial movements may not necessarily be cortically controlled.[49] One study found no difference in facial activity during heel lancing of neonates with and without significant cortical injury, suggesting that facial activity even around 32 weeks' PCA may not represent conscious perception of pain.[50]

Stress Responses. Hemodynamic and neuroendocrine changes in fetuses undergoing stressful procedures have also been used to infer pain perception.[51] As early as 16 weeks' gestational age, fetal cerebral blood flow increases during venipuncture and transfusions that access the fetal hepatic vein through the innervated fetal abdominal wall but not during venipuncture and transfusions involving the noninnervated umbilical cord.[52] Increased cerebral blood flow is not necessarily indicative of pain, as this response is thought to constitute a "brain sparing" mechanism associated with hypoxia[53] and intrauterine growth restriction.[54]

Other investigators measured increases in fetal plasma concentrations of cortisol, β-endorphin, and noradrenaline associated with intrauterine needling procedures, finding that increases during blood sampling from the hepatic vein were greater than those during sampling from the umbilical cord.[55,56] However, these neuroendocrine responses do not constitute evidence of fetal pain,

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because the autonomic nervous system and hypothalamic-pituitary-adrenal axis mediate them without conscious cortical processing.[57] Additionally, these responses are not specific for painful stimuli. Plasma noradrenaline concentrations may increase after umbilical cord transfusion,[58] and plasma β-endorphin concentrations may increase after repeated cordocenteses.[58] Plasma cortisol and β-endorphin concentrations increase during innocuous activities such as exercise.[59] Moreover, in adults, neuroendocrine stress responses may persist despite well-controlled postoperative pain.[60]

Vital signs also have been used to assess neonatal pain.[42,43,45,51,61] However, heart rate, respiratory rate, and transcutaneous oxygen and carbon dioxide levels do not necessarily differ significantly between alcohol-swabbing and lancing the heels of preterm neonates.[80] Another group found that a similar proportion of neonates became hypoxic during tracheal suction, as well as during nonnoxious routine care such as washing and weighing.[62]

Fetal Anesthesia and Analgesia

Anesthetics and analgesics are commonly used to alleviate pain and discomfort. Despite ongoing dehate regarding fetal capacity for pain, fetal anesthesia and analgesia are still warranted for surgical procedures undertaken to promote fetal health. When long-term fetal well-heing is a central consideration, evidence of fetal pain is unnecessary to justify fetal anesthesia and analgesia because they serve other purposes unrelated to pain reduction, including (1) inhibiting fetal movement during a procedure[63-65]; (2) achieving uterine atony to improve surgical access to the fetus and to prevent contractions and placental separation[66-70]; (3) preventing hormonal stress responses associated with poor surgical outcomes in neonates[71,72]; and (4) preventing possible adverse effects on long-term neurodevelopment and behavioral responses to pain.[73-75]

These objectives are not applicable to ahortions. Instead, beneficence toward the fetus represents the chief justification for using fetal anesthesia or analgesia during abortion—to relieve suffering if fetal pain exists. As with any clinical decision, thorough safety and risk-benefit analyses should be undertaken before performing an intervention. Because the principle of beneficence also requires the woman's physician to act in her best interests, potential fetal benefit must be weighed against real risks to the woman's health. The safety and effectiveness of proposed fetal anesthesia and analgesia techniques are discussed below.

General Anesthesia for Fetal Surgery. Fetal surgery involving laparotomy, hysterotomy, or both requires general or regional anesthesia.[68,76] Regional anesthesia, such as epidural anesthesia, does not anesthetize the fetus.[76] General anesthesia is more commonly used because it induces uterine atony and fetal immobilization.[65,77] Studies of inhalational agents in pregnant ewes determined that a dose capable of anesthetizing the ewe also anesthetized the fetus.[78] Administering fentanyl, pancuronium, or vecuronium to the fetus intramuscularly may snpplement analgesia or immobilization.[64,65,77,79]

For pregnant women, general anesthesia is associated with increased morbidity and mortality, particularly because of airway-related complications[80-82] and increased risk of hemorrhage from uterine atony.[70] Historically, general anesthesia was used in abortions, even in the first trimester, until stndies found that general anesthesia was a leading cause of ahortion-related mortality.[83-85] In addition to safety concerns, general anesthesia increases the cost of abortion, making it prohihitively expensive for the majority of patients who pay out of pocket.[86]

Anesthesia and Analgesia in Minimally Invasive Fetal Procedures. In contrast to fetal surgery requiring regional or general anesthesia, minimally invasive fetal procedures do not involve maternal laparotomy or hysterotomy and instead use needles or endoscopy to access the fetus. For the sake of reducing pain, the increased risks of general anesthesia are unjustified for these procedures; adults typically undergo similar procedures with no analgesia or only local analgesia.[87] No established fetal analgesia protocol exists for these procedures, although 3 techniques have been proposed, namely, direct delivery of medications to the fetus, delivery of medications to the fetus via maternal intravenous infusion, and intra-amniotic delivery of medications.

Direct Delivery. One group has examined the effects of analgesics delivered directly to human fetuses during minimally invasive procedures.[87] Twenty-eight fetuses that received intravenous fentanyl before hepatic vein blood transfusions had diminished changes in plasma β-endorphin concentration and cerebral blood flow, compared with fetuses not receiving fentanyl. The cortisol response was not significantly decreased with fentanyl. The investigators did not examine risks for the woman, such as infection or uncontrolled bleeding.[76] Furthermore, reducing the stress response is distinct from reducing pain. For example, plasma glucose and cortisol concentrations may not differ significantly hetween adults with and without postoperative pain.[60]

Delivery via Maternal Intravenous Infusion. To achieve presumably effective fetal plasma concentrations of fentanyl by placental transfer, potentially unsafe doses would need to be administered to the woman.[88] Although standard doses of fentanyl are generally safe for maternal analgesia during labor,[89] fentanyl can pose serious risks such as hypoventilation if maternal doses are significantly increased to achieve more extensive placental transfer.[67,68] Severe maternal hypoventilation may require endotracheal intubation, which increases risks and costs for the woman, as described above.

No data exist on the dosing or efficacy of using medications such as diazepam and morphine for fetal analgesia via maternal intravenous infusion, although studies have characterized the placental transfer of these medications.[90-92] Two related studies found that

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low-dose remifentanil via maternal intravenous infusion achieved fetal immobilization during laser coagulation of placental vessels.[93,94] However, immobilization is not the equivalent of pain reduction, and these procedures did not involve surgery on the fetus.

Intra-amniotic Delivery. Intra-amniotic injection would be technically simpler than direct fetal injection, although the drug must be absorbed through fetal membranes and skin. Intra-amniotic sufentanil injection in 10 pregnant ewes resulted in fetal plasma concentrations that would control postoperative pain in human adults.[95,96] Sufentanil concentrations in the ewes also reached adult human therapeutic concentrations without causing significant hemodynamic changes.[96] However, the study did not evaluate fetal response to noxious stimuli, and no data exist regarding safety or effectiveness in humans.

CONCLUSIONS

Pain is an emotional and psychological experience that requires conscious recognition of a noxious stimulus. Consequently, the capacity for conscious perception of pain can arise only after thalamocortical pathways begin to function, which may occur in the third trimester around 29 to 30 weeks' gestational age, based on the limited data available. Small-scale histological studies of human fetuses have found that thalamocortical fibers begin to form between 23 and 30 weeks' gestational age, but these studies did not specifically examine thalamocortical pathways active in pain perception.

While the presence of thalamocortical fibers is necessary for pain perception, their mere presence is insufficient—this pathway must also be functional. It has been proposed that transient, functional thalamocortical circuits may form via subplate neurons around midgestation, but no human study has demonstrated this early functionality. Instead, constant SEPs appear at 29 weeks' PCA, and EEG patterns denoting wakefulness appear around 30 weeks' PCA. Both of these tests of cortical function suggest that conscious perception of pain does not begin before the third trimester. Cutaneous withdrawal reflexes and hormonal stress responses present earlier in development are not explicit or sufficient evidence of pain perception because they are not specific to noxious stimuli and are not cortically mediated.

A variety of anesthetic and analgesic techniques have been used for fetal surgery, including maternal general anesthesia, regional anesthesia, and administration of medications for placental transfer to the fetus. However, these techniques are not necessarily applicable to abortions. Surgical procedures undertaken for fetal benefit use anesthesia to achieve objectives unrelated to pain control, such as uterine relaxation, fetal immobilization, and possible prevention of neuroendocrine stress responses associated with poor surgical outcomes. Thus, fetal anesthesia may be medically indicated for fetal surgery regardless of whether fetal pain exists.

In the context of abortion, fetal analgesia would be used solely for beneficence toward the fetus, assuming fetal pain exists. This interest must be considered in concert with maternal safety and fetal effectiveness of any proposed anesthetic or analgesic technique. For instance, general anesthesia increases abortion morbidity and mortality for women and substantially increases the cost of abortion. Although placental transfer of many opioids and sedative-hypnotics has been determined, the maternal dose required for fetal analgesia is unknown, as is the safety for women at such doses. Furthermore, no established protocols exist for administering anesthesia or analgesia directly to the fetus for minimally invasive fetal procedures or abortions. Experimental techniques, such as administration of fentanyl directly to the fetus and intra-amniotic injection of sufentanil in pregnant ewes, have not been shown to decrease fetal pain and are of unknown safety in humans.

Because pain perception probably does not function before the third trimester, discussions of fetal pain for abortions performed before the end of the second trimester should be noncompulsory. Fetal anesthesia or analgesia should not be recommended or routinely offered for abortion because current experimental techniques provide unknown fetal benefit and may increase risks for the woman. Instead, further research should focus on when pain-related thalamocortical pathways become functional in humans. If the fetus can feel pain, additional research may lead to effective fetal anesthesia or analgesia techniques that are also safe for women.

Financial Disclosures: None reported.

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The polymorphic visions of the eyes and the spirit are contained in the uniform lines of small or capital letters, periods, commas, parentheses—pages of signs, packed as closely together as grains of sand, representing the many-colored spectacle of the world on a surface that is always the same and always different, like dunes shifted by the desert wind.
—Italo Calvino (1923-1985)

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Fetal Tissue Fallout

R. Alta Charo, J.D.

We have a duty to use fetal tissue for research and therapy.

This statement might seem extreme in light of recent events that have reopened a seemingly long-settled debate over whether such research ought even be permitted, let alone funded by the government. Morality and conscience have been cited to justify defunding, and even criminalizing, the research, just as morality and conscience have been cited to justify not only health care professionals' refusal to provide certain legal medical services to their patients but even their obstruction of others' fulfillment of that duty.

But this duty of care should, I believe, be at the heart of the current storm of debate surrounding fetal tissue research, an outgrowth of the ongoing effort to defund Planned Parenthood. And that duty includes taking advantage of avenues of hope for current and future patients, particularly if those avenues are being threatened by a purely political fight — one that, in this case, will in no way actually affect the number of fetuses that are aborted or brought to term, the alleged goal of the activists involved.

The current uproar was ignited when an antiabortion activist, posing as a biomedical research company representative, captured on video — which he then edited in the most misleading way possible — discussions by Planned Parenthood physicians of the procedures they use (when recovering specific fetal organ tissues) and the cost ($30 to $100 to reimburse for costs). The effect was to portray the organization as callous and possibly criminal in its actions. This orchestrated effort led, predictably, to state and federal calls to end funding for all Planned Parenthood services — more than 95% of which involve such things as contraception and screening for sexually transmitted diseases, rather than abortion.

Along the way, the target broadened, and the use of fetal tissue in research was also attacked. Portrayed as ghoulish vivisection and body-part snatching, it was decried as barbaric by members of Congress. Within weeks, inquiries were announced in Arizona, Indiana, Florida, Kansas, Georgia, Louisiana, Ohio, South Carolina, Tennessee, and Texas; Arizona began looking into making it more difficult to provide tissue; and bills were drafted in Wisconsin and California to make it virtually impossible to use fetal tissue or fetal cells. The inquiries revealed no law broken by Planned Parenthood, but only time will tell how many bills will become law.

A closer look at the ethics of fetal tissue research, however, reveals a duty to use this precious resource in the hope of finding new preventive and therapeutic interventions for devastating diseases. Virtually every person in this country has benefited from research using fetal tissue. Every child who's been spared the risks and misery of chickenpox, rubella, or polio can thank the Nobel Prize recipients and other scientists who used such tissue in research yielding the vaccines that protect us (and give even the unvaccinated the benefit of herd immunity). This work has been going on for nearly a century, and the vaccines it produced have been in use nearly as long. Any discussion of the ethics of fetal tissue research must begin with its unimpeachable claim to have saved the lives and health of millions of people.

Critics point to the underlying abortions, assert that they are evil, and argue that society ought not implicitly endorse them or even indirectly benefit from them, lest it encourage more abortion or make society complicit with what they view as an immoral act. Yet they have overwhelmingly partaken of the vaccines and treatments derived from fetal tissue research and give no indication that they will foreswear further benefits. Fairness and reciprocity alone would suggest they have a duty to support the work, or at least not to thwart it.

The 1988 Fetal Tissue Transplantation Panel, which was appointed by President Ronald Reagan and included a chair and several members who opposed abortion rights, was not persuaded by arguments about complicity. Looking back over decades of research, the panel pointed out that despite fears to the contrary, there was no evidence that the possibility of deriving some good from fetal remains had ever persuaded women to have abortions they otherwise would not have chosen. But to assuage concerns, and to avoid even the theoretical possibility that the benefits of research might encourage an ambivalent woman to choose abortion, the panel recommended that the question of donation not be addressed until after a woman

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had decided she was going to end a pregnancy. It also endorsed the law that prohibited tissue sale for profit (reimbursement of costs was permissible) and recommended that women not be allowed to direct tissue for transplantation to particular people.

Having separated the abortion decision from the choice to donate tissue, the panel concluded that public support is ethical: the source of the tissue poses no moral problem for some people, and in any case, the morality of the two acts can be distinguished.[1] Indeed, as to the claim of complicity, although the Committee on Pro-Life Activities of the National Conference of Catholic Bishops was concerned that the abortion could not in practice be separated from the research, it had written that "it may not be wrong in principle for someone unconnected with an abortion to make use of a fetal organ from an unborn child who died as the result of an abortion."[2] The same arguments led to similar recommendations that have been adopted by European countries.

As it reasoned its way to these recommendations, the panel noted that it is commonplace to use organs and tissues from deceased people, whether their death was caused by accident or homicide. Homicide must surely be viewed as morally evil by anyone who decries the loss of fetal life, and yet no concern is raised about personal or societal complicity with the underlying act. Organ and tissue transplant recipients often talk about the complex emotions that arise from knowing one's own life was saved because another life was taken, but they do not then feel responsible for the other person's death.

The panel also considered the pointlessness of refusing support for this research, which uses fetal tissue that will otherwise be discarded. There are, of course, many avenues of research using other kinds of tissue, but fetal cells can rapidly divide, grow, and adapt to new environments in ways that make them the gold standard for some disease research. And in other research areas, we don't yet know if there is anything that could substitute. Fetal tissue research has already led to investigational therapy for end-stage breast cancer and advances against cardiac causes, and transplantation research is actively being pursued for diabetes (using fetal pancreatic islet cells), amyotrophic lateral sclerosis (using neural fetal stem cells injected into the spine), and in a major European initiative, Parkinson's disease (using fetal dopamine cells).[3]

Given the panel's conclusion that research use of fetal remains is ethical, it seems clear that the needs of current and future patients outweigh what can only be symbolic or political gestures of concern. Indeed, the Vatican's Pontifical Academy for Life, while arguing for a right to refuse to use pediatric vaccines derived from fetal tissue and calling for development of vaccines through other means, nonetheless concluded in 2005 that parents' duty to protect their children from illness justifies their use of current vaccines.

Insofar as this latest threat to basic biomedical research grew out of abortion opponents' longstanding efforts to defund the vast majority of Planned Parenthood's services, such as contraceptive counseling and prescribing,[4] the irony is that reducing access to contraception is the surest way to increase the number of abortions — the inconsistent or incorrect use of contraception accounts for nearly half of the unintended pregnancies each year, and half of those end in abortion.[5]

By using the public's unfamiliarity with the history and realities of fetal tissue research as a back door for attacking Planned Parenthood, abortion opponents have added millions of people to the collateral damage of the abortion wars. This attack represents a betrayal of the people whose lives could be saved by the research and a violation of that most fundamental duty of medicine and health policy, the duty of care.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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OPEN LETTER TO CONGRESS

Stop Politics from Interfering with Science and Research

As scientists committed to improving the health of all people, the undersigned reaffirm our belief that politics has no place in important discussions about research and its role in advancing treatments and cures for diseases and conditions that harm people every day.[1] In the last few months, the use of fetal tissue in research has become a lightning rod for media attention and needless controversy. It is well-established that research using fetal tissue has led to transformative breakthroughs and that it holds promise for future advancements in medicine. We offer our support for the patients, physicians, and researchers that contribute to this vital work, and we call on policymakers to reject attempts to politicize it.

Fetal tissue research has been conducted legally and ethically in the United States for decades. In that time, it has been the catalyst for major medical and scientific discoveries, including the polio, rubella, and hepatitis vaccines. Quite simply: this research has saved lives. If not for the polio vaccine—developed using fetal kidney cells in the 1950s—UNICEF estimates that the disease would claim 640,000 lives each year.[2,3]

Today, the study and use of fetal tissue in medical research gives hope to millions of people and their families affected by a range of diseases and conditions. Fetal tissue is being used to develop treatments for many conditions, including diabetes, Parkinson's disease, Alzheimer's disease, heart disease, stroke, organ failure, and spinal cord injuries.[4] It is also used to better understand and prevent maternal and fetal health conditions.

Fetal tissue research has already saved and improved the lives of countless people. As with any research, we strongly believe that programs involving fetal tissue research must uphold the highest ethical and legal standards. But we cannot allow political agendas to undermine our nation's legacy of leadership in medical and scientific innovation.

Sincerely,

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[1] Affiliated institutions are listed for identification purposes only. The views expressed in this letter are of the individual signatories and do not necessarily reflect the views of the affiliated institutions.
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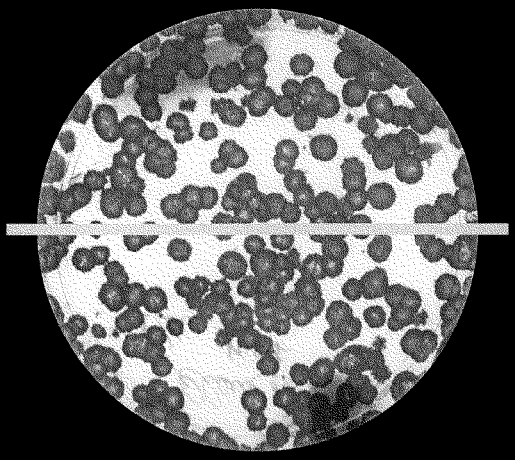

THE TRUTH
ABOUT FETAL TISSUE RESEARCH

The use of aborted fetal tissue has sparked controversy in the United States, but many scientists say it is essential for studies of HIV, development and more.

BY MEREDITH WADMAN

Every month, Lishan Su receives a small test tube on ice from a company in California. In it is a piece of liver from a human fetus aborted at between 14 and 19 weeks of pregnancy.

Su and his staff at the University of North Carolina at Chapel Hill carefully grind the liver, centrifuge it and then extract and purify liver- and blood-forming stem cells. They inject the cells into the livers of newborn mice, and allow those mice to mature. The resulting animals are the only 'humanized' mice with both functioning human liver and immune cells and, for Su, they are invaluable in his work on hepatitis B and C, allowing him to probe how the viruses evade the human immune system and cause chronic liver diseases.

"Using fetal tissue is not an easy choice, but so far there is no better choice," says Su, who has tried, and failed, to make a humanized mouse with other techniques. "Many, many biomedical researchers depend on fetal tissue research to really save human lives," he says. "And I think many of them feel the same way."

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An explosive climate has surrounded US research with fetal tissues since July, when an anti-abortion group called the Center for Medical Progress in Irvine, California, released covertly filmed videos in which senior physicians from the Planned Parenthood Federation of America bluntly and dispassionately discussed their harvesting of fetal organs from abortions for use in research. Planned Parenthood is a non-profit women's health provider that received US$528 million of government money in 2014, much of it in reimbursements for services ranging from contraception to cancer screenings, which it provides largely to poor women. Abortions, which are performed at about half of Planned Parenthood's 700 clinics, constitute 3% of its services. A handful of clinics in two states supply fetal tissue for research.

The videos provoked a furore that has intensified over the past few weeks. On 3 December, the Republican-led US Senate voted to strip Planned Parenthood of government funding. This is despite the fact that fetal tissue research is legal, the US National Institutes of Health (NIH) has been funding it for decades and President Obama is sure to veto the bill, should it reach his desk. A few days earlier, on 27 November, a gunman shot dead three people at a Planned Parenthood clinic in Colorado Springs, Colorado. In a post-arrest interview, the suspect is reported to have said "no more baby parts".

The episode has shone a spotlight on a little-discussed arm of biomedical research, raising the questions of why, how and how widely fetal tissue is used. To find out, *Nature* turned to an NIH database of research grants funded in 2014 to find those using fresh human fetal tissue, and in October contacted 18 researchers working with it. Su was one of only two who were willing to be interviewed. Most requests were declined or went unanswered; a public-affairs officer at one major Texas university refused to have a researcher speak to *Nature* to keep that person "safe".

The figures show that in 2014, the NIH funded 164 projects using the tissue, at a cost of $76 million. This is slightly less than half of what the agency spent on work with human embryonic stem cells (ES cells), which has also been highly controversial, and 0.27% of the $27.9 billion it spent on all research. (By comparison, the UK Medical Research Council spent 0.16% — £1.24 million ($1.9 million) — of its total spending on research on five projects involving fetal tissue in the 12 months up to 31 March 2015.) Analysis of the NIH projects shows that the tissue is used most heavily for research on infectious diseases, especially HIV/AIDS; in the study of retinal function and disease; and in studies of normal and anomalous fetal development (see 'Fetal tissue research by discipline').

> "USING FETAL TISSUE IS NOT AN EASY CHOICE, BUT SO FAR THERE IS NO BETTER CHOICE."

Opponents argue that the work is not necessary because other model systems and techniques can be used. "This is antiquated science," says David Prentice, the vice-president and research director at the Charlotte Lozier Institute, the research arm of the Susan B. Anthony List, which is an anti-abortion organization in Washington DC. "There are better and, frankly, more successful alternatives."

But supporters of the research counter that fetal tissue is legally obtained, that it would otherwise be destroyed, that such work has already led to major medical advances and that, if there were better alternatives, they would turn to them. "Fetal tissue is a flexible, less-differentiated tissue. It grows readily and adapts to new environments, allowing researchers to study basic biology or use it as a tool in a way that can't be replicated with adult tissue," says Carrie Wolinetz, the NIH's associate director for science policy.

"I get very frustrated when misinformed people go on about how it can all be done with computer models or cell cultures or stem cells or animals," says Paul Fowler, a reproductive biologist at the University of Aberdeen Institute of Medical Sciences, UK, who in January published a study using livers from aborted fetuses to probe the impacts of maternal smoking on liver development[1]. "In some areas, the human is absolutely dramatically different than rodents."

Some argue that the entire episode represents a thinly cloaked attempt to attack and limit access to abortion by eroding support and funding for Planned Parenthood. "People are talking about fetal tissue, but really what this discussion is about is abortion," says Shari Gelber, a specialist in maternal–fetal medicine at Weill-Cornell Medical College in New York City, who has argued for the value of the research.

LABORATORY LINES

Cell lines derived from aborted fetal tissue have been fairly commonplace in research and medicine since the creation in the 1960s of the WI-38 cell strain, which was derived at the Wistar Institute in Philadelphia, Pennsylvania, and MRC-5, which came from a Medical Research Council laboratory in London (see *Nature* **498,** 422–426; 2013). Viruses multiply readily in these cells, and they are used to manufacture many globally important vaccines, including those against measles, rubella, rabies, chicken pox, shingles and hepatitis A.

Companies have shipped at least 5.8 billion vaccines made with these two cell lines which, with others, have become standard laboratory tools in studies of ageing and drug toxicity. (Research with such lines is not covered by US regulations governing the use of fresh fetal cells and tissue nor captured in the NIH database.) In the past 25 years, fetal cell lines have been used in a roster of medical advances, including the production of a blockbuster arthritis drug and therapeutic proteins that fight cystic fibrosis and haemophilia.

But off-the-shelf fetal cell lines are of limited use for scientists because they do not faithfully mimic native tissue and represent only a subset of cell types: WI-38 and MRC-5, for example, were derived from fetal lungs. The lines can also accumulate mutations after replicating *in vitro* over time. And creating humanized mice such as Su's requires whole pieces of fetal organs to provide sufficient numbers of stem cells. For all of these reasons, researchers turn to fresh tissue.

In the United States, this is collected at medical centres and clinics that perform abortions under a patchwork of laws and regulations governing consent, tissue collection and transfer (see 'Fetal tissue and the law'). US law says that clinics can recover "reasonable payments" to offset the costs of providing the tissue, but it makes it a felony to profit from doing so. Planned Parenthood officials say that its clinics obtain full and informed consent from women choosing to donate fetal remains for research, and the organization announced in October that its clinics will no longer recover costs of $45–60 per specimen for collecting the tissue.

From the clinics, fetal tissue is then often passed to biological-research supply companies, which act as intermediaries and process the tissue before selling it to researchers. Su pays $830 for each sample of fetal liver tissue supplied to his lab by one of the most widely used suppliers, Advanced Bioscience Resources in Alameda, California.

HIV AND AIDS

The category of fetal tissue work that draws most NIH funding is the study of HIV and AIDS: it accounts for 64 of the 164 NIH grants. Researchers in this field have long struggled with the paucity of effective models for this uniquely human disease. The standard models, macaques, are expensive to breed, are infected with SIV instead of HIV and have immune responses that are different from those of people. The flexibility and adaptability of fetal tissue — and its richness as a

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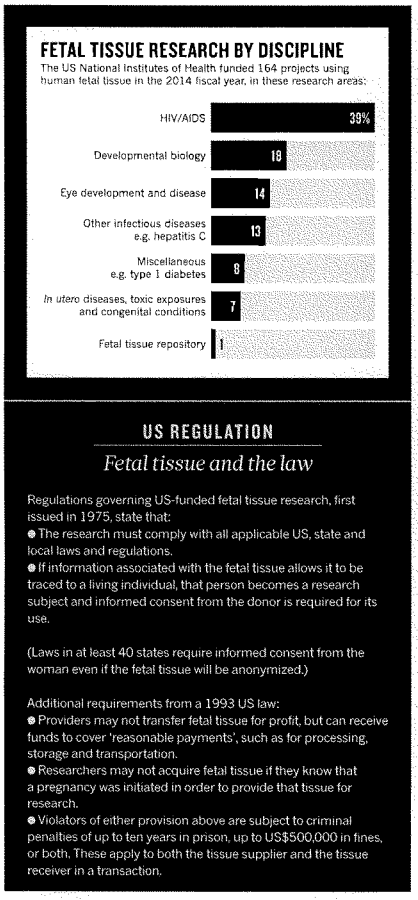

source of stem cells — has allowed the creation of a number of mice with humanized immune systems.

Prominent among these is the BLT (bone marrow–liver–thymus) mouse, which was created in 2006 (ref. 2). This model is made by destroying the animal's immune system and then surgically transplanting liver and thymus tissue fragments from a human fetus into the mouse. The immune system is further humanized with a bone-marrow transplant, using blood-forming stem cells from the same fetal liver. The animal enables studies of, for instance, immune responses that are key to developing an effective HIV vaccine. The mouse has "accelerated the study of HIV pathogenesis and novel approaches to harness anti-viral immunity to control HIV", reads a recent review by several NIH-funded scientists who are using the mouse[3].

The mouse has also helped to demonstrate that prophylactic drugs may prevent vaginal HIV infection — a strategy that is now in late-stage human trials. The animal is currently being used to examine how genital infection with herpes simplex virus alters immunity at the vaginal mucosa, making it easier for HIV to infect. In a similar vein, Su is now using his humanized mouse to examine the mechanisms by which hepatitis C and HIV co-infection can hasten liver disease.

There are drawbacks: the BLT mouse's average lifespan is relatively short, at only around 8.5 months, because the animals tend to develop cancers of the thymus. And the humanized immune system is not inherited, so the model must be created again and again — leading to the constant demand for fetal tissue that so disturbs abortion opponents.

HUMAN DEVELOPMENT

In some research areas, fetal tissue may, in time, be replaced by other materials and methods: alternative, flexible cell types, including human ES cells and induced pluripotent stem (iPS) cells, and organoids, which are lab-created cellular structures that resemble tissue from normal organs (see *Nature* **523**, 520–522; 2015). But there is one area in which, scientists say, fetal tissue is needed by definition: studies of early human development, and why it sometimes goes wrong.

"Human fetal tissue is likely never going to be replaced in some areas of research, particularly relative to fetal development," says Wolinetz. And the application of such work goes far beyond understanding developmental disorders such as congenital heart disease or other malformations, says Neil Hanley, an endocrinologist at the University of Manchester, UK. "For a wide range, now, of adult diseases and disorders, we know that they have their origins during very early human development," he says — type 2 diabetes and schizophrenia are both cases in point. "And unless you understand normal you're not going to understand abnormal."

The 30 developmental-biology grants involving fetal tissue that were awarded by the NIH in 2014 range from a study of the differentiation of myoblasts, which are the embryonic precursors of muscle cells, to several examinations of development of the urogenital tract — studies with relevance, for instance, to hypospadias, a common condition in which the urethra fails to close and the underside of the penis is incompletely formed. One project is creating a three-dimensional atlas of gene expression in the genital tubercle, the precursor of the penis. Another is probing gene activity in cells lining the fetal intestine to help explain excessive intestinal inflammation in premature babies. Hanley says that such studies are important, particularly because gene regulation — the finely tuned symphony that controls when and where genes are active — can vary strikingly between species, so findings in other animals often do not hold true in humans.

More than half of the 30 grants are for studies of brain development, and many of these projects are seeking advances in combating maladies such as autism, schizophrenia and Alzheimer's disease. Larry Goldstein, a neurobiologist at the University of California San Diego School of Medicine in La Jolla, uses cells called astrocytes from the brains of aborted fetuses to nourish neurons that he has derived from iPS cells and that have mutations associated with Alzheimer's disease. The astrocytes are thought to secrete factors that keep the neurons healthy in culture, and he uses the system to study the pathogenesis of the disease and to test potential drugs.

Goldstein hopes eventually to derive the astrocytes, too, from iPS cells. But "the human fetal astrocytes that we get at present are the gold standard that we use, and will use, to compare astrocytes that we make by differentiation", he says. He has also used neurons from aborted fetal brains to compare with the neurons made from iPS cells[4]. "As long as fetal tissue is available, this is a very valuable use of it," he says.

Another 23 of the NIH grants using fetal tissue involve eye development and disease. Damage to the retinal pigment epithelium (RPE), a single layer of cells at the back of the eye, has a key role in a

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ANDY KATZ/GEMOTIX/CORBIS; WIN MCNAMEE/GETTY

The collection of aborted fetal tissue for use in research has prompted demonstrations for and against US health provider Planned Parenthood.

number of eye diseases, including age-related macular degeneration, the most common cause of blindness in adults in the developed world. The 2000s saw advances in ways to create cell cultures with RPE dissected from the eyes of fetuses, allowing scientists to study the function of these cells in a dish. And although some scientists have turned to stem cells to generate RPE, like Goldstein they continue to use fetal tissue as a benchmark of normal development and function.

Goldstein agreed to speak to *Nature*, he says, because "somebody has to speak up responsibly". He stressed that he and his colleagues think hard about the ethics of their work. "We are not happy about how the material became available, but we would not be willing to see it wasted and just thrown away."

Occasionally, fetal tissue is used for clinical work. Last year, a company called Neuralstem in Germantown, Maryland, in collaboration with scientists at the University of California, San Diego, launched a trial in which stem cells from fetal spinal cord were implanted to treat spinal-cord injuries. In May, researchers in the United Kingdom and Sweden launched a study in which dopaminergic neurons from aborted fetuses are transplanted into the brains of patients with Parkinson's disease (see *Nature* **510,** 195–196; 2014). Research with fetal tissue is less controversial in countries where abortion is more widely accepted.

UNCOMFORTABLE VIEWING

The Planned Parenthood videos caused even some supporters of fetal tissue research to feel uncomfortable. In one video, physician Deborah Nucatola, the group's senior director of medical services, describes how she crushes fetuses above and below key organs to preserve them intact for research. She also described turning a fetus into a breech presentation to deliver the head last, when the cervix is more dilated, thus preserving the brain.

This raised the question of whether physicians are altering abortion techniques to accommodate research requests, violating a widely held precept of research ethics. Arthur Caplan, a bioethicist at the New York University School of Medicine, dismisses the videos as "pure politics", but some of the footage "did get my eyebrow to arch", he says. "You can't use a different approach to the abortion to try to preserve something. Those are just no-no's."

Planned Parenthood spokeswoman Amanda Harrington says that the organization is not aware of any instances in which the method of an abortion has been changed to preserve organs. But, she adds, "if minor adjustments that have no bearing on the woman's health and safety are done when the woman has expressed a desire to donate tissue, that is entirely appropriate and ethical and legal". Women's health and safety, she says, "is always the number one priority".

The question for many scientists is what the fallout of the controversy will be. On the heels of the Colorado shootings, some Republicans in Congress backed off earlier attempts to defund Planned Parenthood, and President Obama is expected to veto any bill that does so. This means that the lasting damage of the videos may end up being inflicted not on Planned Parenthood's budget, but on science. Since July, four bills that would criminalize or otherwise restrict the research have been introduced in the US Congress, and lawmakers have launched similar efforts in a dozen state legislatures. (Missouri, Arizona and North Dakota already ban the research.)

Su felt the climate for his research grow colder when, on 1 October, a new North Carolina law was signed that makes it a felony to sell fetal tissue for any amount within the state. Su receives the tissue he uses from outside the state, but the message behind the new law concerns him. "I hope this current controversy, or possible congressional interventions, won't slow down biomedical research," he says. "The benefit is bigger than the drawback on this."

The controversy "absolutely puts fetal tissue research at risk", says Caplan. "Young scientists are unlikely to enter a field riven with controversy, where funding is uncertain and physical threats are a real possibility."

Caplan says that parallels could emerge with events in the early 2000s, when the use of human ES cells in US research became politically fraught. Then, tight federal regulations governing NIH funding of the research were adopted, but some states, including California and Massachusetts, responded by pouring money into the science all the same.

"To move ahead, the reality is that fetal tissue research need not be funded or permitted everywhere," Caplan says. "It needs to be allowed somewhere." ■

Meredith Wadman *is a freelance writer based in Virginia and an editorial fellow at New America, a think tank in Washington DC.*

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CORRECTION

The News Feature 'The truth about fetal tissue research' (*Nature* **528,** 178–181; 2015) incorrectly stated that around 5.8 billion people have received vaccines made with the WI-38 and MRC-5 cell lines. In fact, companies have shipped some 5.8 billion vaccines made with these two cell lines.

No. 15-274

IN THE

Supreme Court of the United States

WHOLE WOMAN'S HEALTH, *et al.*,
Petitioners,

v.

KIRK COLE, M.D., COMMISSIONER OF THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES, *et al.*,
Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF FOR AMICI CURIAE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN MEDICAL ASSOCIATION, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN OSTEOPATHIC ASSOCIATION, AND AMERICAN ACADEMY OF PEDIATRICS IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST OF AMICI CURIAE

The American College of Obstetricians and Gynecologists (the "College" or "ACOG"), the American Medical Association ("AMA"), the American Academy of Family Physicians ("AAFP"), the American Osteopathic Association ("AOA"), and the American Academy of Pediatrics ("AAP") submit this amici curiae brief in support of Petitioners.[1]

ACOG is a non-profit educational and professional organization founded in 1951. The College's objectives are to foster improvements in all aspects of the health care of women; to establish and maintain the highest possible standards for education; to publish evidence-based practice guidelines; to promote high ethical standards; and to encourage contributions to medical and scientific literature. The College's companion organization, the American Congress of Obstetricians and Gynecologists (the "Congress"), is a professional organization dedicated to the advancement of women's health and the professional interests of its members. Sharing more than 57,000 members, including 2,549 obstetrician-gynecologists in Texas, the College and the Congress are the leading professional associations of physicians who specialize in the health care of women.

The College and the Congress recognize that abortion is an essential health care service and oppose laws

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[1] Pursuant to Rule 37.3(a), letters of consent to the filing of this brief are on file with the Clerk of the Court. No counsel for a party authored this brief in whole or in part and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity other than amici or their counsel made a monetary contribution to the preparation or submission of this brief.

regulating medical care that are unsupported by scientific evidence and that are not necessary to achieve an important public health objective.

The College has previously appeared as amicus curiae in various courts throughout the country, including this Court. In addition, the College's work has been cited by numerous courts seeking authoritative medical data regarding childbirth and abortion.

AMA is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policymaking process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in all fields of medical specialization and in every state, including Texas. This Court and the federal courts of appeal have cited the AMA's publications and amicus curiae briefs in cases implicating a variety of medical questions.

AAFP is headquartered in Leawood, Kansas, and is the national medical specialty society representing family physicians. Founded in 1947 as a not-for-profit corporation, its 120,900 members are physicians and medical students from all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Uniformed Services of the United States. The AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and serving the needs of members with professionalism and creativity.

AOA, established in 1897, is the national professional association for the more than 110,000 osteopathic physicians (Doctors of Osteopathic Medicine or DOs) and medical students enrolled in accredited colleges of osteopathic medicine in the United States. This includes more than 3,500 osteopathic physicians who practice in the specialty of obstetrics and gynecology. The AOA is recognized by the United States Department of Education as the accrediting agency for colleges of osteopathic medicine. Since 1943, the AOA's American Osteopathic Board of Obstetrics and Gynecology has offered a program of specialty and subspecialty board certification for osteopathic obstetricians and gynecologists. The AOA is dedicated to promoting public health, to encouraging scientific research, and to maintaining and improving high standards of osteopathic medical education.

AAP was founded in 1930 and is a national, not-for-profit organization dedicated to furthering the interests of child and adolescent health. Since AAP's inception, its membership has grown from 60 pediatricians to more than 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 85 years, AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's families to ensure the availability of safe and effective reproductive health services.

INTRODUCTION AND SUMMARY OF ARGUMENT

Reproductive healthcare is essential to a woman's overall health, and access to abortion is an important component of reproductive healthcare. Amici curiae are leading medical societies, whose policies represent the considered judgments of the many physicians in this country. Amici's position is that laws that regulate abortion should be supported by a valid medical justification. Texas is one of a number of states that have enacted laws that lack such a justification and, if allowed to stand, would restrict access to otherwise safe and professional care.

Passed in 2013, Texas House Bill ("H.B.") 2 requires that abortion facilities—such as outpatient clinics where the majority of abortions in Texas are performed—conform to the standards of ambulatory surgical centers (the "ASC requirement"), notwithstanding that the legal abortions performed in Texas prior to the passage of H.B. 2 met or exceeded safety expectations for outpatient medical procedures. H.B. 2 also requires that abortion providers obtain admitting privileges at local hospitals (the "privileges requirement"), even though such privileges are unnecessary for safe patient care and can be difficult or impossible to obtain for reasons unrelated to a clinician's competence.

Neither requirement is supported by accepted medical practice or scientific evidence. There is no medically sound reason to assume that abortions performed in a hospital or ASC setting are safer than those performed in a clinic or office, and requiring abortion clinics to meet the standards for ASCs has no medical purpose given the nature and simplicity of abortion procedures. The admitting privileges requirement likewise does nothing to improve the health and safety

of women. In fact, it is inconsistent with prevailing medical practice, which provides for continuity of care regardless of whether the clinician has local admitting privileges. Moreover, there is incontrovertible evidence that imposing these unjustified burdens on abortion providers is impeding women's access to quality, evidence-based medicine: H.B. 2 has delayed, and in some cases blocked, women's access to legal abortion. Both outcomes jeopardize women's health.

Patient safety is of paramount concern to amici, and amici support laws that are necessary to protect patient safety. Laws that regulate abortion should be evidence-based and designed to improve women's health.[2] The challenged provisions of H.B. 2 are neither.

ARGUMENT

I. H.B. 2's ASC Requirement Imposes Medically Unnecessary Demands On Abortion Facilities And Serves No Medical Purpose

Contrary to Texas's assertion that abortion procedures would be safer if performed in ASCs,[3] H.B. 2's

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[2] *See, e.g.*, ACOG, Comm. on Health Care for Underserved Women, *Committee Opinion Number 613, Increasing Access to Abortion*, 124 Obstetrics & Gynecology 1060, 1062 (2014) (explaining that the College opposes medically unnecessary physical plant and admitting privileges requirements); ACOG, *College Statement of Policy, Abortion Policy* 2 (2014) (opposing "unnecessary regulations that limit or delay access to care"); *see also* ACOG, *Statement of Policy, Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (2013).

[3] Pet. App. 25a ("The Texas Legislature's stated purpose for enacting these provisions was to raise the standard and quality of care for women seeking abortions and to protect the health and welfare of women seeking abortions."); Opp. 3, 24; Resp. C.A. Br. 13, 35-36.

requirement that abortion facilities[4] meet the standards for ASCs lacks any evidence-based medical or scientific justification.[5]

A. Abortion Is An Extremely Safe Medical Procedure And No Medical Evidence Suggests That Abortion Would Be Safer If Performed In An ASC Setting

Abortion is one of the safest medical procedures performed in the United States. The risk of death resulting from an abortion has been exceptionally low for decades. Between 1978 and 2007, the national mortality rate, as reported in five-year periods by the Centers for Disease Control and Prevention, ranged from 0.52 per 100,000 (or 0.00052 percent) to 0.78 per 100,000 (or 0.00078 percent).[6] Between 2008 and 2011, the most recent period for which data is available, the national

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[4] Under Texas law, the term "abortion facility" applies to providers of abortions, such as outpatient clinics, that are not hospitals, ASCs, or physicians' offices (unless the office performs more than fifty abortions in any twelve-month period). Tex. Health & Safety Code Ann. § 245.004; *Whether Abortion Facilities that are Exempt from Licensing Under Section 245.004 of the Health and Safety Code are Subject to Regulation by the Texas Department of Health Under Chapter 245*, Op. No. GA-0212, at 1 & n.4 (Tex. Att'y Gen. July 7, 2004). In this brief, amici use the terms "facilities" and "clinics" interchangeably.

[5] Amici are aware that, in 2003, Texas enacted a law providing that abortions at sixteen weeks of gestation and later be performed only in ASCs or hospitals. Tex. Health & Safety Code Ann. § 171.004. Amici confine their statements here to abortions occurring prior to sixteen weeks of gestation, which were performed legally in clinics and physicians' offices prior to the enactment of H.B. 2.

[6] Pazol et al., *Abortion Surveillance—United States, 2012*, 64 Morbidity & Mortality Wkly. Rep. 1, 11, 40 tbl. 23 (2015).

mortality rate was 0.73 per 100,000 (or 0.00073 percent).[7]

Publicly available data suggest that the abortion-related mortality rate in Texas prior to H.B. 2's full implementation was even lower than these national figures. According to Texas's own vital statistics, 993,844 abortions were performed between 2001 and 2013 (the years for which data is available online).[8] Only five deaths were reported in this thirteen-year period, accounting for a mortality rate of 0.5 per 100,000 (or 0.0005 percent).[9] From 2009 through 2013, there were no reported deaths in 360,059 abortions performed in Texas.[10]

The risk of major complications from the procedure is similarly low. In a comprehensive review of published studies, researchers found that most studies re-

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[7] *Id.*

[8] The calculations in the text accompanying this note and several subsequent notes are based on annual abortion statistics compiled by the Texas Department of State Health Services ("DSHS") in its *Vital Statistics Annual Reports*, http://www.dshs.state.tx.us/chs/vstat/annrpts.shtm (last updated Oct. 15, 2015).

[9] *Id.*

[10] *Id.* By contrast, in 2011 (the latest year graphed by DSHS), the average maternal mortality rate in Texas was 24.4 per 100,000 live births (or 0.0244 percent); for black women, that rate was 67.3 per 100,000 (or 0.0673 percent). DSHS, *2014 Healthy Texas Babies: Data Book* 14 fig. 21 (2014). Similarly, one nationwide study found that the mortality risk associated with childbirth is approximately fourteen times higher than the risk associated with abortion. Raymond & Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216-217 & tbl. 1 (2012) (analyzing data from 1998 to 2005).

ported a less than 0.5 percent risk of hospitalization following a first-trimester aspiration abortion.[11] The higher rates of hospitalization reported in some studies were associated with procedures done using general anesthesia, which is infrequently used for first-trimester aspiration abortions in office-based clinics in the United States.[12] Indeed, one recent U.S.-based study found that the risk of major complications (uterine perforation, infection, and hemorrhage) from first-trimester aspiration abortions—the most common abortion procedure in Texas—is just 0.05 percent.[13]

Moreover, there is no medically sound reason to assume that abortions performed in a hospital or ASC setting are safer than those performed in a clinic or of-

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[11] White et al., *Complications from First-Trimester Aspiration Abortion: A Systematic Review of the Literature*, 92 Contraception 422, 434, 435 tbl. 7 (2015). The rate of major complications across all abortion procedures, including medication and second-trimester abortions, is similarly low. *See* Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 176 fig. 1, 181 (2015) (using 2009-2010 data from California and finding a 0.23 percent risk of abortion complications that might require hospital admission, surgery, or blood transfusion).

[12] White et al., *supra* note 11, at 434.

[13] Weitz et al., *Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver*, 103 Am. J. Pub. Health 454, 458 & tbl. 2 (2013) (using 2007-2011 data from California); DSHS, *Vital Statistics Annual Reports*, *supra* note 8 (data by type of procedure); *see also* White et al., *supra* note 11, at 434 ("Major complications following first-trimester aspiration abortion were very rare").

fice.[14] The above-referenced comprehensive review of research found that "the percentage of abortions that resulted in major complications necessitating intervention was not higher in office-based clinics compared to ASCs and hospital-based clinics but rather was similar across settings."[15] Texas's mortality statistics point to the same conclusion. In the five years during which Texas had no reported abortion-related deaths, the overwhelming majority of abortions—83 percent—were performed in outpatient clinics or physicians' offices, not in ASCs or hospitals.[16] From 2001 to 2013, when Texas statistics reflected an exceedingly low mortality rate of 0.5 per 100,000 abortions (or 0.0005 percent), 91 percent of abortions were performed in outpatient clinics or physicians' offices.[17] Nationally, 95

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[14] Peacock et al., *Transition to Office-Based Obstetric and Gynecologic Procedures: Safety, Technical, and Financial Considerations*, 58 Clinical Obstetrics & Gynecology 418, 427 (2015) ("[F]irst-trimester aspiration abortions performed in an office are as safe as those performed in hospitals."); Paul, *Office Management of Early Induced Abortion*, 42 Clinical Obstetrics & Gynecology 290, 292 (1999) ("Compared with hospital-based procedures, abortions in ambulatory settings are comparably safe[.]"); *see also* Grimes et al., *Abortion Facilities and the Risk of Death*, 13 Fam. Plan. Persp. 30, 31 (1981) (mortality rates for first-trimester abortions are similar for hospitals and nonhospital facilities); Grimes et al., *Comparative Risk of Death from Legally Induced Abortion in Hospitals and Nonhospital Facilities*, 51 Obstetrics & Gynecology 323, 324 (1978) (same).

[15] White et al., *supra* note 11, at 435. White and her colleagues also concluded that "legislation requiring facilities where abortions are performed to meet ASC standards is unlikely to lead to measurable improvement in complications from first-trimester aspiration abortion." *Id.*

[16] DSHS, *Vital Statistics Annual Reports*, *supra* note 8.

[17] *Id.*

percent of abortions are performed in nonhospital settings.[18]

In sum, outpatient clinics and physicians' offices are safe places to obtain abortions.[19] Amici are aware of no medical basis for a mandate that abortion clinics meet the standards for ASCs.

B. H.B. 2's ASC Requirement Imposes Medically Unnecessary Demands On Abortion Facilities

Requiring that an abortion clinic meet the standards for ASCs has no medical purpose because of the nature and simplicity of abortion procedures. ASCs are meant to provide environments in which invasive surgeries historically performed in hospitals can be performed outside a hospital-based setting. Abortion procedures, however, do not require an incision into a woman's body and do not expose sterile tissue to the external environment. The performance of such procedures thus does not require a hospital-based or related outpatient setting. Nor is there any medical purpose or principled reason for Texas law to require abortion facilities, but not other facilities that perform similar or riskier outpatient procedures, to meet ASC standards.

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[18] Rock & Jones, *TE Linde's Operative Gynecology* 783 (10th ed. 2011); Peacock et al., *supra* note 14, at 427 (same); *see also* Joyce, *The Supply-Side Economics of Abortion*, 365 New Eng. J. Med. 1466, 1466-1467 (2011) (94 percent of all abortions take place in clinics).

[19] *See* ACOG, *Frequently Asked Questions, Induced Abortion* 1 (2015); *see also* Rock & Jones, *supra* note 18, at 783.

1. Abortion procedures do not require the full operating theater or external sterility precautions that are mandated by H.B. 2

The physical plant requirements mandated by H.B. 2—such as the presence of an operating room—are medically unnecessary for abortion procedures. As an initial matter, an increasingly large percentage of early abortions are medication abortions rather than surgical abortions.[20] No designated procedure space is required for medication abortions because the procedure involves administering prescription pills that induce pregnancy termination, which then typically occurs at home.[21]

Even surgical abortions, however, do not require an operating room. To conduct a first-trimester surgical abortion, the clinician has the patient recline on an examination table, taking the same position as for many gynecological exams. Few personnel are involved; little is required by way of equipment. The procedure is not commonly performed using general anesthesia, so designated space for related equipment storage is not generally required.[22] Surgical abortions simply do not require the size, layout, or equipment of a full operating

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[20] Pazol et al., *supra* note 6, at 8 (use of early medication abortion increased from 8.5 percent of abortions in 2003 to 20.4 percent in 2012).

[21] *See* ACOG, *Practice Bulletin Number 143, Medical Management of First-Trimester Abortion*, 123 Obstetrics & Gynecology 676, 677-678 (2014) (providing current evidence-based guidelines for medication abortion).

[22] In any event, as noted below, Texas law does not require that procedures using general anesthesia be performed in a facility that meets ASC standards. *See infra* note 30 and accompanying text.

theater. In this respect, they are no different than many procedures used for the management of miscarriages, which are also commonly addressed in office settings.[23]

Moreover, many of the burdensome construction requirements contained in the ASC regulations that are designed to maintain a sterile environment—such as restricted-access surgical suites, one-way traffic flow patterns, scrub equipment, and special ventilation units—are unnecessary in abortion clinics.[24] This is because clinicians performing abortions access the uterus through the vagina, which is known as a "clean-contaminated field" and is not naturally a sterile space. Therefore, "[r]outine sterile precautions (e.g., drapes, caps, masks, and gowns) are unnecessary"[25] under accepted medical practice for abortions. Indeed, accepted medical practice requires only that the clinician use sterile instruments and "ensure[] that the tips of instruments never contact non-sterile surfaces before entering the uterus."[26]

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[23] *See infra* note 29 and accompanying text.

[24] One specific example of a structural element designed to maintain a highly sterile environment in ASCs that is superfluous in the abortion context is the requirement that ASCs have operating rooms with ceilings that are "monolithic from wall to wall ... , smooth and without fissures, open joints, or crevices and with a washable and moisture impervious finish." 25 Tex. Admin. Code § 135.52(f)(5)(C). While such a requirement may be advisable for procedures where sterile body tissue is exposed, abortions are not such procedures and such stringent construction regulations are unnecessary.

[25] Rock & Jones, *supra* note 18, at 784.

[26] Lohr & Lyus, *Dilatation and Evacuation*, in *Abortion Care* 88, 95 (Rowlands ed., 2014); *see also* Paul, *supra* note 14, at 294.

Respondents' argument before the court of appeals—that the external sterility requirements for ASCs are beneficial to abortion procedures because "surgical abortion involves invasive entry into the uterus"[27]—ignores the fact that, unlike some other obstetric and gynecological procedures (such as cesarean deliveries and abdominal hysterectomies), surgical abortions do not involve exposure of the uterus to the external environment. For this reason (among others), ensuring the sterility of the portions of the surgical instruments that make contact with the uterus is sufficient to achieve the sterility needed for the procedure. There is simply no credible argument that the sterility precautions mandated by H.B. 2 have an accepted scientific or medical basis.

2. Office-based surgery is common and Texas law does not require that facilities performing procedures with higher mortality rates than abortion meet the standards for ASCs

Office-based surgery is common, and for many gynecological procedures it is the prevailing practice.[28]

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[27] *See* Pet. App. 31a; Resp. C.A. Br. 13.

[28] *See, e.g.*, ACOG, *Patient Education Pamphlets: Colposcopy* (2013); ACOG, *Patient Education Pamphlets: Hysteroscopy* (2011); ACOG, *Patient Education Pamphlets: Endometrial Hyperplasia* (2012); ACOG, *Patient Education Pamphlets: Loop Electrosurgical Excision Procedure* (2013); Allen et al., *Pain Relief for Obstetric and Gynecologic Ambulatory Procedures*, 40 Obstetrics & Gynecology Clinics N. Am. 625, 631-640 (2013) (colposcopy, cervical biopsy, cervical dilation and uterine aspiration, IUD insertion, endometrial biopsy, hysteroscopy); Nichols et al., *A Comparative Study of Hysteroscopic Sterilization Performed In-Office Versus a Hospital Operating Room*, 13 J. Minimally Inva-

For example, incomplete miscarriages are commonly treated in office settings via uterine aspiration, which is the same procedure as that used for the majority of induced abortion procedures affected by H.B. 2.[29]

Indeed, consistent with accepted medical practice, Texas permits physicians to perform surgical and other procedures in an office setting, including surgical procedures that require general anesthesia (which generally increases a procedure's risk), and/or that have complication and mortality rates similar to or higher than those associated with abortion, without requiring that

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sive Gynecology 447, 449 (2006) (demonstrating the "feasibility and suitability of performing hysteroscopic sterilization in-office"); Peacock et al., *supra* note 14, at 425-431 (hysteroscopy, IUD retrievals, sterilization, uterine evacuation (including dilation and aspiration), among other procedures); Urman et al., *Safety Considerations for Office-Based Obstetric and Gynecologic Procedures*, 6 Revs. Obstetrics & Gynecology e8, e14 (2013) ("There is no evidence to substantiate office-based gynecologic procedures being inherently unsafe. On the contrary, gynecologists can perform procedures in the office setting in a safe, effective, efficient, patient-centered fashion.").

[29] Allen et al., *supra* note 28, at 632 (uterine aspiration is used for induced abortion and treatment of miscarriages and can be performed in an office setting); Dennis et al., *Barriers to and Facilitators of Moving Miscarriage Management Out of the Operating Room*, 47 Persp. on Sexual & Reprod. Health 141, 141, 143-144 (2015) (technical aspects of miscarriage management and induced abortion are the same); Peacock et al., *supra* note 14, at 427 (vacuum curettage is used for abortion and miscarriage management and can be performed in office setting); Godfrey et al., *Early Pregnancy Loss Needn't Require a Trip to the Hospital*, 58 J. Fam. Prac. 585, 588 (2009) (vacuum aspiration appropriate for office setting); DSHS, *Vital Statistics Annual Reports*, *supra* note 8 (data by procedure type).

the offices meet ASC standards.[30] For example, no law requires colonoscopies or liposuction to be performed in an ASC or hospital setting, despite the fact that the mortality rate for both procedures is higher than for abortion. The mortality rate for colonoscopy, for example, is 0.007 percent, ten times higher than the national mortality rate for abortion.[31] The mortality rate for liposuction is even higher, at approximately 0.02 percent.[32]

There is no medical purpose or principled reason for Texas law to require abortion facilities—but not other medical facilities that perform similar or riskier outpatient procedures—to meet ASC standards.

II. H.B. 2's PRIVILEGES REQUIREMENT DOES NOT SERVE THE HEALTH OF WOMEN IN TEXAS

As with the ASC requirement, the Texas legislature's claimed purpose for requiring abortion providers to maintain admitting privileges at a local hospital is "to raise the standard and quality of care for women seeking abortions and to protect the health and welfare of

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[30] *See* 22 Tex. Admin. Code §§ 192.1-192.6 (providing guidelines for office-based use of different levels of anesthesia, including general anesthesia).

[31] Am. Soc'y for Gastrointestinal Endoscopy, *Complications of Colonoscopy*, 74 Gastrointestinal Endoscopy 745, 747 (2011). For a discussion of the low mortality rate associated with abortion, *see supra* notes 6-10 and accompanying text.

[32] Grazer & de Jong, *Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons*, 105 Plastic & Reconstructive Surgery 436, 441 (2000).

women seeking abortions."[33] But H.B. 2's privileges requirement provides no medical benefit and is inconsistent with prevailing medical practice. Clinicians may be denied admitting privileges for reasons unrelated to the quality of care they provide, and developments in modern medical practices, which emphasize communication between physicians who specialize in inpatient or outpatient settings, achieve continuity of care without regard to whether a woman's abortion provider has admitting privileges. Stated in plain terms, the privileges requirement does nothing to improve the health and safety of women.

A. Clinicians Are Denied Medical Privileges For Reasons Unrelated To Their Competency

Obtaining privileges can be difficult, if not impossible, for many clinicians, irrespective of the clinician's technical competence. For example, some academic hospitals will only allow medical staff membership for clinicians who also qualify for and accept faculty appointments. Other hospitals require that clinicians admit a certain number of patients, or perform a certain number of deliveries or major obstetric or gynecological surgeries in order to affiliate with the hospital. Providers who specialize in performing abortions are frequently unable to meet such requirements because abortion is a very safe procedure only rarely resulting in hospitalization.[34]

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[33] Pet. App. 25a (citing S. Comm. on Health & Human Servs., Bill Analysis, Tex. H.B. 2, 83d Leg., 2d C.S. 1 (2013)); Opp. 3, 22.

[34] *See, e.g.*, White et al., *supra* note 11, at 435 ("[S]ince the percentage of women requiring hospitalization is very low, physicians will be admitting few (if any) patients, which may make it difficult for them to maintain hospital privileges.").

These factors can—and do—result in a denial of admitting privileges. In this very case, the Fifth Circuit credited evidence that clinicians at Petitioner's clinic in McAllen have been denied privileges for reasons unrelated to their competency.[35] But the real-life impact of the privileges requirement is far more wide-ranging than the effect on the McAllen clinic. After H.B. 2's privileges requirement went into effect, nearly one-third of abortion clinics were forced to stop providing abortions.[36] Requiring that clinicians obtain hospital privileges—when such privileges may be denied for reasons unrelated to the quality of care that they provide—does not promote the wellbeing of Texas women.

B. H.B. 2's Privileges Requirement Is Inconsistent With Accepted Medical Practice And Provides No Benefit To Patient Care Or Health Outcomes

The privileges requirement is also inconsistent with prevailing medical practices, which achieve continuity of care independent of whether the clinician who performs the abortion has admitting privileges at a lo-

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[35] Pet. App. 70a-71a ("With respect to the admitting privileges requirement, Whole Woman's Health presented considerable evidence that Plaintiff Dr. Lynn and three unidentified physicians working at the McAllen facility were unable to obtain admitting privileges at local hospitals for reasons other than their competence."). There was also evidence in the record that a clinician from Petitioner's El Paso clinic was denied privileges for reasons unrelated to clinical competence, but the Fifth Circuit found it unnecessary to consider this evidence in reaching its decision. *Id.* at 72a & n.44.

[36] Grossman et al., *The Public Health Threat of Anti-Abortion Legislation*, 89 Contraception 73, 74 (2014).

cal hospital.[37] Rather than requiring admitting privileges, accepted medical practice requires the abortion provider's facility to have a plan to provide prompt emergency services and (if needed) to transfer a patient to a nearby emergency facility if complications occur.[38] This practice ensures that, in the rare instance where a woman experiences a complication during or immediately after an abortion and needs hospital-based care,[39] she can be treated appropriately by a trained emergency-room clinician or the hospital's on-call specialist.[40] The care provided by that emergency-room clinician or on-call specialist occurs without regard to whether the woman's abortion provider has admitting privileges.

In fact, the transfer of care from the abortion provider to an emergency-room clinician is consistent with the broader practice throughout modern medicine for

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[37] *See* Inst. of Med., *Crossing the Quality Chasm: A New Health System for the 21st Century* 8-9 (2001) (recommending that health care be available 24 hours a day and that "[c]linicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care").

[38] ACOG, *Guidelines for Women's Health Care: A Resource Manual* 720 (4th ed. 2014) ("Clinicians who perform abortions ... should have a plan to provide prompt emergency services if a complication occurs and should establish a mechanism for transferring patients who require emergency treatment."); Nat'l Abortion Fed'n, *2015 Clinical Policy Guidelines* 42 (2015) (similar protocols).

[39] *See supra* notes 11-13 and accompanying text for a discussion of the rarity of abortion-related complications.

[40] *See* White et al., *supra* note 11, at 435 ("In the rare event that a hospital transfer is needed, the clinician who is most qualified to treat a woman experiencing a major complication may not be the one who performed the abortion.").

inpatient and outpatient care to be provided by practitioners who specialize in each setting.[41] It is no longer the case that the same clinician necessarily provides both outpatient and hospital-based care; rather, hospitals increasingly rely on "hospitalists" who provide care only in a hospital setting.[42] Communication and collaboration between specialized health care providers achieves continuity of care.[43] Indeed, prior to the enactment of H.B. 2, Texas law reflected the prevailing medical practice by requiring that abortion facilities have protocols to ensure that patients could be transferred to a hospital in the rare event of an emergency requiring hospital treatment.[44]

H.B. 2's privileges requirement also does nothing to assist Texas women in the rare event that they experience complications after returning home. As with any emergency, it is likely that a woman would seek treatment at her nearest hospital at the time it occurs.[45] Given the juxtaposition of H.B. 2's requirement that an abortion provider maintain privileges at a hospital within thirty miles of her clinic with the fact that the average Texas county is 111 miles from an abortion

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[41] *See, e.g.*, ACOG, Comm. on Patient Safety & Quality Improvement, *Committee Opinion Number 459, The Obstetric-Gynecologic Hospitalist*, 116 Obstetrics & Gynecology 237 (2010).

[42] *Id.* at 237.

[43] *See* Inst. of Med., *supra* note 37, at 9, 62, 133-134.

[44] 38 Tex. Reg. 6536, 6546 (Sept. 27, 2013) (requiring a "readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital," including a "working arrangement" with a physician who has admitting privileges at a local hospital).

[45] Upadhyay et al., *supra* note 11, at 176.

clinic,[46] it is unlikely that the hospital at which a woman seeks emergency medical care will be the hospital at which her provider maintains privileges. Nor would it be appropriate to transport a woman an additional distance to a hospital simply because that is the facility at which her abortion provider maintains privileges.[47]

There is thus no medical basis from which to conclude that women's health would be advanced by requiring that clinicians obtain the local privileges mandated by H.B. 2. Indeed, such a requirement is out of step with prevailing medical practice and imposes an unnecessary restriction on the ability of clinicians to provide abortion care.

Several federal courts have noted the lack of scientific basis for similar privileges requirements. In November, the U.S. Court of Appeals for the Seventh Circuit permanently enjoined enforcement of a substantially identical privileges requirement in a Wisconsin statute.[48] As relevant here, the court explained that "complications from an abortion are both rare and rarely dangerous" and "[a] woman who experiences complications from an abortion (either while still at the clinic where the abortion was performed or at home after-

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[46] Soffen, *How Texas Could Set National Template for Limiting Abortion Access*, N.Y. Times, Aug. 19, 2015, http://nyti.ms/1E36Zjc.

[47] Indeed, H.B. 2 elsewhere acknowledges that the prevailing practice is for a patient to receive emergency care at a facility near her home. Tex. Health & Safety Code Ann. § 171.0031(a)(2)(B) (requiring that a woman be given "the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated").

[48] *See Planned Parenthood of Wis., Inc.* v. *Schimel*, 806 F.3d 908 (7th Cir. 2015).

ward) will go to the nearest hospital, which will treat her regardless of whether her abortion doctor has admitting privileges."[49] It thus "makes no sense," the court concluded, "to abridge the constitutional right to an abortion on the basis of spurious contentions regarding women's health."[50]

In setting aside Alabama's privileges requirement, the U.S. District Court for the Middle District of Alabama found that mandating that abortion providers have local admitting privileges "falls outside the range of standard medical practice for complication care" for abortion procedures and "would, in reality, undermine the State's goal of continuity of care" because women in

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[49] *Id.* at 912.

[50] *Id.* at 920. Judge Manion dissented, citing in part a 2004 statement joined by amici AMA and ACOG, for the proposition that "admitting privileges" are a "core principle" of patient safety. *Id.* at 928 (Manion, J., dissenting). As the plain language of the 2004 statement makes clear, however, it is a core principle for physicians to have admitting privileges *or* a transfer agreement (with another physician or hospital) in place. *See id.* (discussion quoting Am. Coll. Surgeons, *Statement on Patient Safety Principles for Office-Based Surgery Utilizing Moderate Sedation/Analgesia, Deep Sedation/Analgesia, or General Anesthesia*, 89 Bull. Am. Coll. Surgeons 32, 33 (2004)). In Wisconsin, as in Texas, laws that predate the admitting privileges requirements mandate such agreements. *Id.* at 909 (majority opinion); *supra* note 44. Moreover, ACOG's recent publications, which reflect advances in accepted medical practices, make clear that ACOG does not recommend an admitting privileges requirement for abortion procedures. *See supra* note 2; ACOG, *Report of the Presidential Task Force on Patient Safety in the Office Setting* (2010) (compiling recommendations for office-based surgery, none of which require admitting privileges at a nearby hospital).

Alabama would lose local access to the clinics forced to close under the privileges requirement.[51]

As these courts have recognized, citing the relevant standards of care, a privileges requirement is unnecessary and provides no benefit to women's health.

III. H.B. 2 Jeopardizes Women's Health By Restricting Access To Safe And Legal Abortion

Not only are H.B. 2's ASC and privileges requirements entirely unnecessary, there is incontrovertible evidence that they are impeding women's access to quality abortion care. That these restrictions are making abortion more difficult and expensive to obtain, imposing new burdens on women who can least afford them, is amply documented by Petitioners and other amici.[52] Amici here write separately to address the several ways in which these burdens are known to jeopardize women's health.

At the outset, it is beyond question that delays in obtaining an abortion can compromise a woman's health; abortion should be performed safely and as early as possible.[53] That is true notwithstanding that abortion procedures are among the safest medical pro-

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[51] *Planned Parenthood Se., Inc.* v. *Strange*, 33 F. Supp. 3d 1330, 1372 (M.D. Ala.), *supplemented by* 33 F. Supp. 3d 1381 (M.D. Ala.), *and amended by* 2014 WL 5426891 (M.D. Ala. Oct. 24, 2014).

[52] *See* Pet. Br. 23-26, 49-50; *see also, e.g.*, Soffen, *supra* note 46 (noting that the average Texas county is 111 miles from a facility that provides abortions; if the Fifth Circuit's judgment is allowed to stand, the typical cost of an abortion in Texas would rise 15 percent, to $701).

[53] *See* ACOG, *College Statement of Policy, Abortion Policy*, *supra* note 2, at 2.

cedures. Complications, as rare as they are, increase with the length of the pregnancy.[54] The mortality rate for abortions occurring prior to thirteen weeks of gestation, the period during which most abortions are performed,[55] is no more than 0.4 per 100,000.[56] The mortality rate increases significantly, however, throughout the second trimester to 1.7 per 100,000 when the abortion is performed between thirteen and fifteen weeks, 3.4 per 100,000 when the abortion is performed between sixteen and twenty weeks, and 8.9 per 100,000 when the abortion is performed at twenty-one weeks or later.[57]

Research confirms that, following the enactment of H.B. 2, women have been prevented from obtaining timely and legal abortions. During the first six months following the implementation of H.B. 2's privileges requirement, when nearly one-third of Texas's clinics closed, there was a noticeable increase in the proportion of abortions performed in the second trimester, as compared with the prior twelve-month period,[58] exposing those women to risks above what they would have

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[54] *See* Bartlett et al., *Risk Factors for Legal Induced Abortion-Related Mortality in the United States*, 103 Obstetrics & Gynecology 729, 735 (2004).

[55] Pazol et al., *supra* note 6, at 1 (noting that "nearly all" abortions are performed at or prior to thirteen weeks of gestation).

[56] Bartlett et al., *supra* note 54, at 733 tbl. 2.

[57] *Id.*; *see also* Grossman et al., *Complications After Second Trimester Surgical and Medical Abortion*, 16 Reprod. Health Matters 173, 173 (2008) (citing the Bartlett data).

[58] Grossman et al., *Change in Abortion Services After Implementation of a Restrictive Law in Texas*, 90 Contraception 496, 498-499 & tbl. 1 (2014).

experienced had they obtained abortions earlier in their pregnancies.[59] During that same period, the number of abortions reported in Texas declined by 13 percent, which researchers observed was a steeper drop "than that reported for both Texas and the nation in recent years."[60] The number of abortions reported in the Lower Rio Grande Valley—the home of a particularly vulnerable population of women—declined even further.[61]

Amici are concerned that these declines may indicate not a true reduction in the incidence of abortion, but rather, among other possibilities (such as obtaining care in another state), a rise in illegal abortions, including self-induced abortions. Data suggest that there is a relationship between restricted access and the use of unsafe means to end an unwanted pregnancy, and self-induction puts women at risk for injury or death caused by, among other things, fake or expired medications, improper dosage, lack of instructions, trauma, or the absence of medical supervision.[62]

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[59] *See* Grossman et al., *Public Health Threat*, *supra* note 36, at 74.

[60] Grossman et al., *Change in Abortion Services*, *supra* note 58, at 499 tbl. 1, 500.

[61] *See id.* at 499. For women in the Valley, the decline may deepen even more because approximately half of women from the Valley who obtained abortions during this time period did so at a clinic in Corpus Christi, which has since closed. *See id.*

[62] *See* ACOG, *Committee Opinion Number 613*, *supra* note 2, at 1061 ("[H]istorical and contemporary data show that where abortion is illegal or highly restricted, women resort to unsafe means to end an unwanted pregnancy, including self-inflicted abdominal and bodily trauma, ingestion of dangerous chemicals, self-medication with a variety of drugs, and reliance on unqualified

A statewide survey of Texas women in January 2015 found that self-induction was more likely to occur among Latinas who live in a county bordering Mexico and women who reported difficulty obtaining reproductive health services due to barriers such as the cost of services or difficulty arranging transportation.[63] "Given that [both] populations ... are among those that have been most directly affected by the closure of abortion clinics in the state [due to H.B. 2]," the researchers found cause to "suspect that abortion self-induction will increase as clinic-based care becomes more difficult to access."[64] The record evidence in this case points in the same direction. The court of appeals credited abortion providers' testimony "regarding the difficulties that women in the Rio Grande Valley faced after the McAllen facility ceased performing abortions, including that the clinic saw an increase in self-attempted abortion."[65]

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abortion providers."); Shah et al., *Access to Safe Abortion: Progress and Challenges Since the 1994 International Conference on Population and Development (ICPD)*, 90 Contraception S39, S40 (2014) (noting that "legal restrictions result in women self-inducing abortion or seeking it clandestinely"); Grossman et al., *Public Health Threat*, *supra* note 36, at 74 ("Evidence from other countries indicates that severely restricting abortion does not reduce its incidence—it simply makes unsafe abortion more common.").

[63] Grossman et al., *Knowledge, Opinion and Experience Related to Abortion Self-Induction in Texas*, Texas Policy Evaluation Project Research Brief 2, 4 (2015).

[64] *Id.* at 4.

[65] Pet. App. 65a; *see also* Hellerstein, *The Rise of the DIY Abortion in Texas*, The Atlantic, June 27, 2014, http://www.theatlantic.com/health/archive/2014/06/the-rise-of-the-diy-abortion-in-texas/373240/ (reporting on self-induction in the Rio Grande Valley).

In sum, far from safeguarding women's health, requirements imposed by H.B. 2 jeopardize women's health by impeding, if not outright preventing, access to safe, legal, evidence-based abortion care. Amici oppose laws that, in the absence of any valid medical justification, have this potentially devastating result.[66]

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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[66] *See* ACOG, *College Statement of Policy, Abortion Policy*, *supra* note 2, at 2.

ISSCR

INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH

ISSCR ENDORSES FETAL TISSUE RESEARCH AS ESSENTIAL

The International Society for Stem Cell Research (ISSCR) is the world's leading professional organization of stem cell scientists, representing more than 4,000 members in 45 U.S. states and 65 countries around the world. The ISSCR is opposed to recent efforts to inappropriately limit or prohibit biomedical research using fetal tissue. These proposals, if enacted, would obstruct critical biomedical research and inhibit efforts to improve human health. If enacted in the past, such limits would have delayed or prevented the development of therapies that have saved millions of lives.

Research using donated fetal tissue has been underway since the 1930s and has made major contributions to our understanding of biology and the development of new medical technologies. Fetal tissue is obtained from spontaneous miscarriages and legal abortions. In each case, the fetal tissue would be discarded if not donated by patients for medical research. With the consent of donors, this unique and valuable tissue can be used for research into basic biological processes and human development, as well as creating new treatments for life-threatening diseases.

Fetal tissue is an essential "gold-standard" resource that enables laboratory-based research into how human tissues and organs develop. While other approaches, such as using animal models and cells from adults, can be helpful, for some congenital and developmental conditions it is necessary to study human fetal tissues. For example, without fetal tissue research, it would not be possible to fully understand congenital defects in the heart or nervous system, and new therapies for diseases that affect these tissues would be delayed or prevented.

Further, some of the most important fetal tissue research has involved the use of fetal cell lines in developing vaccines for many diseases, including measles, mumps, rubella, chicken pox, diphtheria, tetanus, whooping cough, polio, hepatitis A, hepatitis B, rabies, shingles, and adenovirus infections. Millions of lives have been saved as a result of this research. The development of the polio vaccine, which relied on the use of cultured cells from fetal tissue, has prevented hundreds of thousands of cases of polio each year and was recognized with a Nobel Prize in 1954. The April 25, 2014 U.S. Center for Disease Control and Prevention's Morbidity and Mortality Report estimated that as a result of childhood immunizations, there were 322 million fewer illnesses, 21 million fewer hospitalizations, and 732,000 fewer deaths among children born in the United States between 1994 and 2013 (http://www.cdc.gov/mmwr/pdf/wk/mm6316.pdf#12). A great many of these lives were saved as the result of research using fetal tissue.

In addition to their historical role in vaccine development, the U.S. National Institutes of Health recognizes the use of fetal tissue in research into maternal health, premature births, and infant health as "irreplaceable". Premature infants often show delays in neural development, affecting memory, thought, and language. Using fetal brain tissue, researchers have discovered that the production of new brain cells, which normally continues throughout fetal development, is impaired by premature birth. This discovery makes it possible to explore new approaches

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to promote normal brain cell development in premature babies. Our understanding of the causes of retinopathy of prematurity, a leading cause of blindness in premature infants, has been advanced by fetal tissue research.

Fetal tissue has also allowed researchers to test cell-based approaches to a variety of neurodegenerative diseases that do not have any other effective treatment. Clinical trials of these fetal tissue-derived cells are currently ongoing for amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), spinal cord injury, stroke, and age-related macular degeneration.

In closing, fetal tissue research has led to many new insights into human development as well as therapies that have saved millions of lives. Ongoing access to human fetal tissue that has been obtained legally and with donor consent is required to address many important questions in biomedical research and for the development of new therapies. The ISSCR endorses fetal tissue research as essential to the prevention and treatment of life-threatening diseases.

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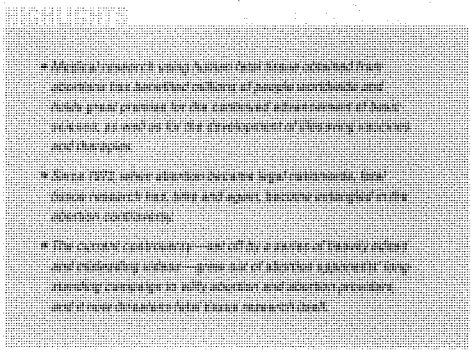
Fetal Tissue Research: A Weapon and a Casualty in the War Against Abortion

By Heather D. Boonstra

The debate over using human fetal tissue in medical research came roaring back on the national policy agenda last summer when a group of antiabortion activists began releasing deceptively edited videos about Planned Parenthood's handling of fetal tissue donations for this purpose. Fetal tissue research dates back to the 1930s, and has led to major advances in human health, including the virtual elimination of such childhood scourges as polio, measles and rubella in the United States.[1,2] Today, fetal tissue is being used in the development of vaccines against Ebola and HIV, the study of human development, and efforts to treat and cure conditions and diseases that afflict millions of Americans.



To ensure it meets the highest ethical standards, fetal tissue research has been subject to stringent laws and regulations for decades. Abortion foes are now accusing health care providers and researchers of violating these laws and ethical standards, in hopes of undermining the right to abortion and ending fetal tissue research. These attacks not only threaten sexual and reproductive health and rights, but also pose a threat to the large numbers of people who could benefit from fetal tissue research, given the wide range of conditions that such research might ameliorate. Any impediment to ongoing scientific inquiry in the field caused by the current controversy would have substantial consequences.

Importance of Fetal Tissue Research

Unlike embryonic stem cell research, which uses cells from days-old embryos created through in vitro fertilization, fetal tissue research uses tissue derived from induced abortion of pregnancies at or after the ninth week.[1,3] (Fetal tissue obtained from a miscarriage is often not suitable for research purposes because of concerns about potential chromosomal abnormalities that led to the miscarriage.[3]) Researchers most often acquire fetal tissue from a tissue bank or, sometimes, directly from a hospital or abortion clinic.[4]

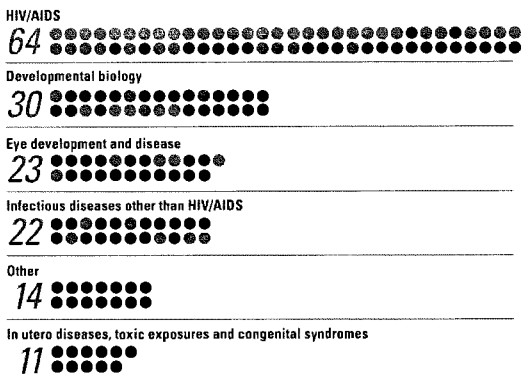
Because it is not as developed as adult tissue and is able to adapt to new environments, fetal tissue is critical to the study of a wide variety of diseases and medical conditions, according to the American Society for Cell Biology.[1] Researchers use fetal tissue—and cell cultures derived from such tissue, which can be maintained in a laboratory environment for decades—to study fundamental biological processes and fetal development. According to the U.S. Department of Health and Human Services, fetal tissue continues to be an important resource for researchers studying degenerative

eye disease, human development disorders such as Down syndrome, and early brain development (relevant to understanding the causes of autism and schizophrenia).[2]

Fetal tissue has also been used to develop vaccines that have saved and improved the lives of billions of people worldwide.[1,2,5] The 1954 Nobel Prize in Medicine was awarded for work using cell cultures originating from fetal tissue that led to the development of the polio vaccine. Vaccines for diseases such as measles, mumps, rubella, chickenpox, whooping cough, tetanus, hepatitis A and rabies were also created using fetal cell cultures, and researchers are now using fetal cells to develop vaccines against other diseases, including Ebola, HIV and dengue fever.

WIDESPREAD APPLICATIONS

The National Institutes of Health provides grants for a wide array of fetal tissue research projects.



Note: Data are for fiscal year 2014. *Source: Nature.*

In addition, researchers use fetal tissue in transplantation research. Fetal tissue has several unique properties that make it particularly suitable for transplantation. Not only do fetal cells grow at a much faster rate than adult cells, they also elicit less of an immune response, which lowers the risk of tissue rejection.[6] Clinical trials transplanting fetal cells are currently underway for people with spinal cord injury, stroke and ALS (Lou Gehrig's disease), and may soon begin for those with Alzheimer's disease, Parkinson's disease and multiple sclerosis.[1]

The National Institutes of Health (NIH) has been supporting research using fetal tissue since the 1950s, and in FY 2014, NIH provided roughly $76 million for this work.[3] According to an analysis of NIH research grants published in *Nature*, NIH funded 164 projects using fetal tissue in 2014, most often for research on infectious diseases, eye function and disease, and developmental biology (see chart).[7,8]

Many of the nation's leading academic medical centers are involved in fetal tissue research.[7,9,10] Researchers at the University of North Carolina at Chapel Hill are using cell cultures derived from fetal tissue for their work on hepatitis B and C—specifically, on how the viruses evade the human immune system and cause chronic liver diseases. At the University of Wisconsin-Madison, fetal cell cultures are used to study heart disease, including sudden cardiac arrest. At Stanford University, fetal tissue has been used to study Huntington's disease, juvenile diabetes, autism and schizophrenia. And scientists at Colorado State University are conducting HIV research using fetal tissue.

Federal Law and Regulation

Soon after the U.S. Supreme Court's *Roe v. Wade* decision in 1973 legalizing abortion nationwide, antiabortion leaders in Congress seized on fetal tissue research as a weapon in the war against abortion. Fetal tissue research was perhaps an inevitable target: It provided an aura of legitimacy to abortion itself and, at the same time, could be easily exploited to show how abortion "dehumanizes"

the fetus.[11] Accordingly, antiabortion activists employed graphic visuals to shock members of Congress, try to personify the fetus, and demonize abortion providers and the procedure itself.

This first incarnation of the controversy coincided with public revelations about the infamous Tuskegee syphilis study—a study that enrolled black men living in Alabama to investigate the long-term effects of syphilis. In 1973, an ad hoc advisory panel convened by the Department of Health, Education and Welfare (now the Department of Health and Human Services) concluded that, in retrospect, the study was "scientifically unsound" and "ethically unjustified."[12] In response to the Tuskegee revelations, Congress felt pressure to create protections for human research subjects, and by 1974, Congress passed the National Research Act. The law created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to develop guidelines on the ethical principles that apply to research on all human subjects, as well as on particular principles that apply to research involving fetuses and using fetal tissue.

The commission's report on research on the fetus, issued in 1975, led to the creation of regulations during the Ford administration that set out the rules of the road for federally funded fetal tissue research. The regulations—which are still in effect—specify that "no inducements, monetary or otherwise, will be offered to terminate a pregnancy." They also provide that "individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy."

Fetal tissue research receded as a political issue until the late 1980s, when a group of NIH scientists sought approval from the Reagan administration for a proposed project involving the transplantation of fetal tissue. After deliberating on the request, the administration appointed an advisory panel—which included a chair and several members who were well-known opponents of abortion rights—to examine the ethical, legal and scientific questions raised by this type of research. In 1988, the panel issued its report and, despite its mixed composition, it concluded that "in light of the fact that abortion is legal and that the research in question is intended to achieve significant medical goals...the use of such tissue [for research] is acceptable public policy."[13]

Key recommendations of the panel were later codified into law with the passage of the NIH Revitalization Act of 1993. The legislation won broad bipartisan support in Congress, including from several prominent senators with solid anti-abortion records. Among them were Sens. Robert Dole (R-KS), a longtime advocate for people with disabilities, and Strom Thurmond (R-SC), who had a daughter with juvenile diabetes.[14,15]

The NIH Revitalization Act of 1993 added several provisions to the existing regulations governing fetal tissue research. One such provision prohibits anyone from accepting payment for human fetal tissue other than "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue." Thus, although individuals may be compensated for any costs they incur in the acquisition, receipt or transfer of fetal tissue, they are prohibited from making a profit from these activities, regardless of whether the project is federally funded or not.

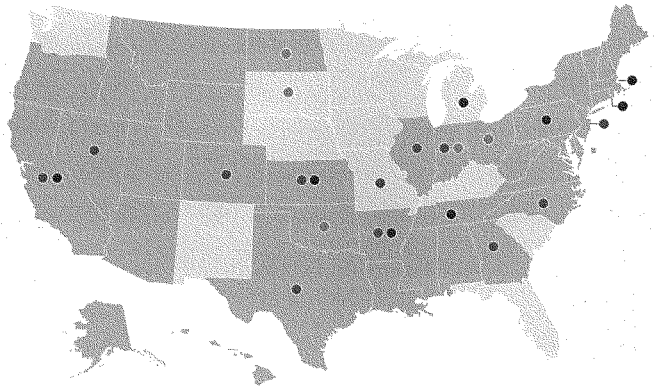
The law also imposes additional requirements when the donated tissue is used in federally funded research involving the transplantation of fetal tissue for therapeutic purposes. Among these are provisions for informed consent and prohibiting physicians and researchers from altering the timing or method used to terminate the pregnancy solely for the purposes of obtaining the tissue. Although all of these requirements technically apply only to federally funded transplantation research, as a practical matter, they set the standard for all research using fetal tissue. For example, the policies and procedures for fetal tissue donation issued by Planned Parenthood Federation of America and by the National Abortion Federation incorporate the substance of these federal requirements.[16,17]

State Policies

At the state level, fetal tissue donation is regulated by the Uniform Anatomical Gift Act (UAGA),

FETAL TISSUE POLICIES

In the states, fetal tissue donation is generally governed by the Uniform Anatomical Gift Act (UAGA). In addition, many states have specific statutes on fetal tissue donation and research.



- Donation explicitly permitted under UAGA (TOTAL = 38+DC)
- Donation not addressed under UAGA (TOTAL = 12)
- Prohibits profiting from fetal tissue donation or procurement (TOTAL = 12)
- Requires consent before fetal tissue is donated (TOTAL = 8)
- Bans all fetal tissue research (TOTAL = 5)

Note: Three additional states have laws that apply only to abortion after viability. Kentucky prohibits experiments using tissue from a postviability abortion. Nebraska and Wyoming prohibit "giving away, sale, transfer or distribution" of tissue from a postviability abortion.

versions of which are in effect in every state.[13,18] According to an analysis by the Guttmacher Institute, 38 states and the District of Columbia have UAGA laws that explicitly treat fetal tissue the same way as other human tissue, permitting it to be donated by the woman for research, therapy or education. The remaining 12 states have laws that are silent, neither allowing nor disallowing the donation of fetal tissue (see map). UAGA also prohibits profiting from the sale or purchase of anatomical gifts for transplantation or therapy.

Fetal tissue donation and research are also regulated in some states by specific statutes. Often, these statutes incorporate many of the same standards set by federal law and regulations. For example, 12 states prohibit making a profit from the donation or transfer of fetal tissue for research purposes, and eight states require the woman's consent for research.

Five states have laws that ban research using fetal tissue obtained from abortions throughout pregnancy. (Four other states also ban research using postabortion fetal tissue, but these laws have been struck down by the courts.) One of these states with a ban in effect, Indiana, also has a law that requires the disposal of postabortion fetal tissue in an established cemetery or by cremation, presumably precluding any possibility of donation for research.

Political Firestorm

The current furor over the use of fetal tissue in research ignited last summer, after the release of heavily edited videos purporting to capture undercover sting operations targeted at Planned

Parenthood. The series of videos—released in close cooperation with members of Congress who want to ban abortion[19]—show an antiabortion activist posing as a representative of what turned out to be a sham biomedical research company, in frank discussions with various Planned Parenthood officials about tissue donation policies and reimbursement.

The fallout from the videos has been swift, severe and wide-ranging. The stated targets are Planned Parenthood, abortion providers and the legitimacy of abortion. The videos also threaten to undermine fetal tissue research itself, however, by sowing confusion, and by using graphic descriptions and images to turn the public against this research.

The primary goal of this current campaign has been to portray Planned Parenthood as callous and its providers as possibly criminal. Antiabortion policymakers have accused Planned Parenthood of violating several provisions of the NIH Revitalization Act of 1993, such as profiting from the sale of fetal tissue and altering the abortion procedure solely for the purpose of obtaining tissue. Opponents of abortion have also accused providers of using a procedure that violates the so-called "partial birth" abortion ban. As an instigator of the videos, David Daleiden explained in an interview with *Politico*, "For me, the goal was to document and illustrate for the public really, really clearly how Planned Parenthood harvests and sells the body parts of the babies that they abort."[20]

Antiabortion elected officials ran with this narrative and immediately called for investigations of the organization. In October 2015, congressional leaders formed a special committee to carry out an official inquiry into Planned Parenthood—bringing the total number of investigations into Planned Parenthood in the House and Senate to five since the first video was released. In January 2016, the House's first substantive piece of business was yet another attempt to cut off funding for Planned Parenthood, one of several such efforts recently to scale back abortion rights and women's health care. Also, officials in 11 states have concluded investigations into claims that Planned Parenthood profited from fetal tissue donation, and each one of these investigations has cleared the organization of wrongdoing.[21]

Nonetheless, the grandstanding has continued unabated. Antiabortion leaders, lawmakers and all the Republican presidential candidates have used the opportunity to demonize abortion and paint a ghoulish picture of organ harvesting, all in an effort to gin up public disgust and attract public support for themselves and against abortion and Planned Parenthood. Indeed, the videos and the hype around them appear to have provoked at least four arson attacks on Planned Parenthood clinics since July 2015 and set the stage for yet another extreme act of violence in Colorado Springs over Thanksgiving weekend.[10] It was there that Robert Lewis Dear Jr. allegedly killed three people and injured nine others at a Planned Parenthood health center. During his arrest, Dear shouted "no more baby parts," suggesting that the constant barrage of inflammatory rhetoric around the fetal tissue issue over the prior months played a role in triggering his actions.[22]

High Stakes

Beyond the attacks on Planned Parenthood, however, the use of fetal tissue in research also is under direct attack. Since July, bills have been introduced in Congress and in several states that would make it more difficult to donate tissue or use fetal tissue in research. Other bills would ban fetal tissue research outright. This trend is almost certain to continue through 2016 as the issue is sure to be exploited in state and federal elections.

Meanwhile, the videos appear to have had a chilling effect on science. According to Theresa Naluai-Cecchini, a scientist at the Birth Defects Research Laboratory at the University of Washington (a federally funded entity that has served as a source of donated fetal tissue to researchers nationwide for more than 50 years), tissue donations have dropped dramatically since July 2015.[10] Naluai-Cecchini told *Mother Jones* that if this trend continues, research that may save lives would take considerably longer.

Some scientists involved in fetal tissue research have been afraid to speak out.[7] They have seen how abortion providers have been targeted,

and now they too fear for their personal safety. Others have spoken out strongly to defend the importance of their work, pointing out that tissue that would otherwise be discarded has played a vital role in lifesaving medical advances and holds great promise for new breakthroughs. In an October 2015 open letter to Congress, 41 scientists called for the end to political interference with science and research: "Fetal tissue research has already saved and improved the lives of countless people. [We] cannot allow political agendas to undermine our nation's legacy of leadership in medical and scientific innovation."[23] In another action, the Association of American Medical Colleges released a statement on January 6, 2016 signed by 59 academic medical centers, scientific societies and allied groups—from the University of Alabama School of Medicine to Duke University School of Medicine, from the University of Wisconsin-Madison toTulane University School of Medicine.[24]The statement expresses "grave concerns" about the numerous legislative proposals now in play in Congress and in many states, and it calls on lawmakers to reject any proposals that restrict access to fetal tissue for research.

Ironically, in the wake of all the heightened focus on fetal tissue donation, Planned Parenthood officials report they have seen an uptick in the number of women obtaining abortion who request that the fetal tissue be donated to research. The role that Planned Parenthood plays in providing postabortion tissue to researchers, however, is small: Just 1% of the approximately 700 health centers that are part of the Planned Parenthood network are equipped for fetal tissue donation. And in another response to the disinformation campaign and to try to quell some of the controversy, Planned Parenthood announced in October 2015 that its clinics will no longer seek reimbursement for their costs related to fetal tissue donation, even though the practice is perfectly legal and commonplace.

Bioethicist R. Alta Charo has argued that enabling the use of fetal tissue to advance scientific research for the benefit of humankind must be seen as something of a moral imperative. "Virtually every person in this country has benefited from research using fetal tissue," she wrote in the *New England Journal of Medicine*. "Every child who's been spared the risks and misery of chickenpox, rubella, or polio can thank the Nobel Prize recipients and other scientists who used such tissue in research yielding the vaccines that protect us....Any discussion of the ethics of fetal tissue research must begin with its unimpeachable claim to have saved the lives and health of millions of people."[25]

As the full impact of the current firestorm surrounding fetal tissue research is still unfolding, it remains to be seen how much this research will continue be used as a weapon against abortion or become a serious target itself—or both. To be sure, the current controversy threatens not just access to safe and legal abortion and the providers who care for the women who seek this essential health service. It also threatens the millions of people globally who could benefit from fetal tissue research—and that includes nearly all of us, whatever our views on abortion rights may be. ■

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March 1, 2016

Select Investigative Panel of the Energy and Commerce Committee
US House of Representatives
Washington, DC 20515

Dear Members of the Select Panel,

We, the 31 undersigned national faith-based and religious groups, stand with the organizations and individual healthcare professionals that provide women with quality medical services and comprehensive reproductive care, including abortion. Representing millions of people of faith committed to ensuring women's health and moral autonomy, we are deeply troubled by the latest deplorable attacks on the providers of a legal medical procedure. We urge you to end the investigation into abortion providers and turn your efforts to protecting a woman's ability to make her own faith-informed decisions about her health and her access to safe care.

As people of diverse faith traditions, we understand the myriad beliefs and moral complexity that exist on issues of reproductive health—abortion in particular. In keeping with our nation's principle of religious liberty, we respect the right of each individual to hold their own beliefs. However we feel about abortion, it is not our place to interfere in a woman's personal decision. It is also not the place of legislators to interfere by seeking to push safe, legal abortion out of reach, yet that is the goal of the deceptive campaign advanced by the Center for Medical Progress. The smear campaign videos and specious claims against abortion providers were created using dishonest and possibly illegal tactics and have been widely discredited. By validating this smear campaign, we believe the Select Panel will provoke vitriol rather than further productive discourse. It shows a disturbing lack of concern for women's health and safety, wastes taxpayer dollars and is simply another tactic to eliminate vital health options for women.

The truth is, fetal tissue research has been deemed appropriate public policy, receiving strong bipartisan support in the past. If a woman makes the compassionate decision to donate fetal tissue to support life-saving medical research, her decision should be respected and accommodated when possible. Fetal tissue donated for use in critical biomedical research has led to critical breakthroughs and is currently helping find cures for diseases like Parkinson's and Alzheimer's.

Our organizations share a faith-centered commitment to the most marginalized and the most vulnerable of our society, including those with limited financial means or those who live in areas with limited access to healthcare and related services. Our organizations respect women's moral agency and are committed to the social good. We value compassion and feel obligated to protect women's health and well-being. We also value religious liberty, which upholds the right of each person to make their own faith-informed or conscience-based healthcare decisions.

As groups representing millions of people of faith—including those who access healthcare at local Planned Parenthood health centers, women's health clinics and from independent abortion providers across the country—we affirm our support for the incredible and necessary work of these caring health professionals. We call on you to reject the underhanded and dishonest attempts to discredit abortion providers by an organization with a singular goal: to deny access to critical reproductive health services.

As organizations of faith, we stand with those who provide women with comprehensive reproductive healthcare with compassion and consideration rather than judgment. As members of Congress committed to supporting the health and well-being of your constituents, we urge you to do the same.

Sincerely,

A Critical Mass: Women Celebrating Eucharist
Anti-Defamation League
Bend the Arc: A Jewish Partnership for Justice
Catholics for Choice
Central Conference of American Rabbis
Concerned Clergy for Choice
CORPUS
Episcopal Women's Caucus
Hadassah, The Women's Zionist Organization of America, Inc.
Hindu American Foundation
International Rabbinical Assembly
Jewish Alliance for Law and Social Action
Jewish Council for Public Affairs
Jewish Women International
Keshet
Methodist Federation for Social Action
Muslims for Progressive Values
National Coalition of American Nuns (NCAN)
National Council of Jewish Women
New Ways Ministry
Reconstructionist Rabbinical College and Jewish Reconstructionist Communities
Religious Coalition for Reproductive Choice
Religious Institute
Society for Humanistic Judaism
Union for Reform Judaism
Unitarian Universalist Association
Unitarian Universalist Women's Federation
Women of Reform Judaism
Women's Alliance for Theology, Ethics and Ritual (WATER)
Women's League for Conservative Judaism
Women's Rabbinic Network

For additional information on this letter, please contact Sara Hutchinson Ratcliffe, Catholic for Choice domestic program director, at shratcliffe@catholicsforchoice.org or 202-986-6093;
or Amy Cotton, National Council of Jewish Women senior policy manager, at amy@ncjwdc.org or 202 375 5067.

STATEMENT ON THE SELECT PANEL TO ATTACK WOMEN'S HEALTH
March 1, 2016

We write as organizations deeply opposed to the continued attacks on science, medical research, and women's health care by the House Energy and Commerce Committee's Select Panel to Attack Women's Health (the Panel).

This Panel is part of a sustained systemic effort to cut off women's access to health care, including safe, legal abortion care. In the 114th Congress, congressional leadership has held nine votes to defund Planned Parenthood—including one vote that took place just days after a devastating mass shooting at a Planned Parenthood health center in Colorado—and launched five separate investigations into Planned Parenthood and related issues.

This harmful campaign is premised on nothing more than discredited videos released by extremists opposed to abortion. Planned Parenthood and other abortion providers[1] have been cleared of wrongdoing in numerous venues, including a grand jury that set out to investigate Planned Parenthood in Houston, Texas, but instead indicted the makers of these videos.[2] Even more telling, the twelve states that have launched investigations have turned up no evidence of wrongdoing. An additional eight states decided not to open an investigation at all, citing the lack of credible evidence.[3] Yet, this reckless campaign against women's health continues unabated.

The Panel's destructive fishing expedition targets science and critical life-saving medical research. Fetal tissue research has long contributed to major medical breakthroughs that have saved countless lives—including infant lives—such as vaccines for polio, chicken pox, measles, and rubella.[4] Today, scientists use fetal tissue to study a wide range of devastating health conditions, from degenerative diseases like Parkinson's to AIDS.[5] This Panel should not politicize science that has immeasurably reduced human suffering and holds tremendous promise for the future. Attacking this medical progress is irresponsible and contradicts the Panel's purported "focus" on improving infant lives. If the Panel were truly invested in addressing issues impacting infant lives, it would not have scheduled its March 2 hearing at the exact time as an Energy and Commerce subcommittee hearing on the Zika virus—a pressing public health crisis that is impacting women and infants in our hemisphere.

Moreover, we are deeply concerned that the Panel has made sweeping requests for detailed personal information that would identify researchers, health care providers, medical residents, students, and others. The Panel has refused to adopt any procedural safeguards to protect personal information from inadvertent disclosure, meaning that it could become public without any recourse. Public identification poses grave privacy and security concerns and would expose these individuals to more harassment, intimidation, and physical harm. In fact, health care providers and women seeking health care at facilities that offer reproductive health care are already facing an alarming increase in threats, harassment, and attacks. Since the release of the highly edited and misleading videos in July 2015, three people were killed and nine were injured during an attack in Colorado Springs, Colorado, and four reproductive health care facilities have been targets of arson.[6] No health care professional or researcher should have to fear for their lives for providing healthcare or conducting critical life-saving research.

We oppose the Panel's politicized campaign against abortion care, just as we oppose all the dangers the campaign presents to women in our country and their health care providers. We urge the Panel to end its attacks on science, medicine, and women.

Advocates for Youth
American Civil Liberties Union
American Society for Reproductive Medicine
Association of Reproductive Health Professionals
Catholics for Choice
Center for Reproductive Rights
Hadassah, The Women's Zionist Organization of America, Inc.
Methodist Federation for Social Action
NARAL Pro-Choice America
National Abortion Federation
National Center for Lesbian Rights
National Council of Jewish Women
National Family Planning & Reproductive Health Association
National Latina Institute for Reproductive Health
National Partnership for Women & Families
National Women's Health Network
National Women's Law Center
People For the American Way
Physicians for Reproductive Health
Planned Parenthood Federation of America
Population Institute
Religious Institute
Reproductive Health Technologies Project
Secular Coalition for America
Sexuality Information and Education Council of the U.S. (SIECUS)
URGE: Unite for Reproductive & Gender Equity

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[1] After watching 504 hours of video, Judge Orrick of the U.S. District Court for the Northern District of California issued a preliminary injunction preventing the release of this footage wherein he wrote "I have reviewed the recordings relied on by defendants and find no evidence of criminal wrongdoing." National Abortion Federation v. The Center for Medical Progress et al. Case No. 3:15-cv-03522-WHO Document 354.

[2] Manny Fernanadez, *2 Abortion Foes Behind Planned Parenthood Videos Are Indicted*, N.Y. TIMES, Jan. 25, 2016, http://www.nytimes.com/2016/01/26/us/2-abortion-foes-behind-planned-parenthood-videos-are-indicted.html.

[3] *The Planned Parenthood witch hunt*, WASH. POST, Feb. 20, 2016, https://www.washingtonpost.com/opinions/the-planned-parenthood-witch-hunt/2016/02/20/a6cb0e5c-d660-11e5-b195-2e29a4e13425_story.html.

[4] *See, e.g.*, Malcolm Ritter, *Human fetal tissue long used for variety of medical studies*, ASSOCIATED PRESS, July 29, 2015, http://bigstory.ap.org/article/e0980d2780ff4e4ca9ee17903b5b5dc8/human-fetal-tissue-long-used-variety-medical-studies; Meredith Wadman, *The Truth about Fetal Tissue Research*, SCIENTIFIC AMERICAN, Dec. 9, 2015, http://www.scientificamerican.com/article/the-truth-about-fetal-tissue-research/; Carina Storrs, *How exactly fetal tissue is used for medicine*, CNN, Nov. 30, 2015, http://www.cnn.com/2015/07/17/health/fetal-tissue-explainer/.

[5] *Id.*

[6] National Abortion Federation Motion for Preliminary Injunction. National Abortion Federation v. The Center for Medical Progress et al. Case No. 3:15-cv-3522-WHO Document 234-3.

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

Office of the President
Mark S. DeFrancesco, MD, MBA, FACOG

March 1, 2016

The Honorable Marsha Blackburn
Chair, Select Investigative Panel of the Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Janice Schakowsky
Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Representatives Blackburn and Schakowsky:

On behalf of the American Congress of Obstetricians and Gynecologists (ACOG), representing more than 57,000 physicians and partners in women's health, I am writing today to in support of women's access to comprehensive health care, including reproductive care, and in support of the continued use of fetal tissue for medical research.

As women's health care physicians, we recognize that safe, legal abortion is a necessary component of women's health care. Where abortion is legal, it is extremely safe. In contrast, where abortion is illegal or highly restricted, women resort to unsafe means, including self-inflicted abdominal and bodily trauma, ingestion of dangerous chemicals, self-medication with a variety of drugs, and reliance on unqualified providers.[1]

We urge the Panel members to focus on important, even urgent, measures that must be taken to protect women and infants, including strengthening the U.S. public health response to the Zika virus, an emergent public health threat.

Fetal tissue research has been credited for propelling scientific understanding of diseases such as polio, hepatitis A and measles. Given what we know thus far about exposure to the Zika virus during pregnancy and the potential link to birth defects, fetal tissue research may play a fundamental role in the development of a vaccine.

We urge Panel members, and the full Congress, to work together on meaningful ways to improve women's health care.

Sincerely,

Mark S. DeFrancesco, MD, MBA, FACOG
President

[1] Increasing access to abortion. Committee Opinion No. 613. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;124:1060–5.

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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Fayetteville, GA

March 1, 2016

The Honorable Marsha Blackburn
Chair, Select Investigative Panel of the Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Janice Schakowsky
Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Representatives Blackburn and Schakowsky:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 64,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, I write express support for necessary medical research conducted using fetal tissue.

In the last century, medical research has led to numerous scientific advances that have drastically improved the lives of children. Perhaps none of these advances have been more impactful than the development of vaccines. It is estimated that for just the children born between 1994 and 2013, "vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the course of their lifetimes." Chicken pox, hepatitis A, polio, rabies, and rubella vaccines are grown in human cell cultures developed from two cell lines that were derived from fetal tissue in the 1960s. Fetal tissue research has played an integral role in the vaccine development that has saved millions of lives throughout history.

Fetal tissue can help researchers replicate human systems that cannot otherwise be replicated. This type of research has helped improve our understanding of numerous health issues including early brain development, neurocognitive disorders, congenital heart defects, Down syndrome, and other infectious diseases such as HIV/AIDS and influenza. As with any research, fetal tissue research must be conducted consistent with appropriate ethical standards. Given the substantial historical and future potential benefit on child health, the AAP strongly supports continued federal funding for fetal tissue research.

Sincerely,

Benard P. Dreyer, MD, FAAP
President

BPD/jdb

Association of
American Medical Colleges
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March 1, 2016

As leading academic medical centers and scientific and medical societies who conduct and support life-saving research, we have grave concerns about legislative proposals to restrict the use of fetal tissue for research.

From therapies for end-stage breast cancer, diabetes, and Parkinson's disease to a promising vaccine for Ebola, vital medical research depends on continued use of fetal tissue under current laws and regulations. Fetal tissue continues to be an important resource for biomedical research. Fetal tissue is used when scientists need a cellular system that is less differentiated than adult cells. According to the U.S. Department of Health and Human Services, "fetal tissue continues to be a critical resource for important efforts such as research on degenerative eye disease, human development disorders such as Down syndrome, and infectious diseases, among a host of other diseases." Since the 1930's, fetal tissue has been used in a broad range of research that has led to lifesaving discoveries. In the past, human fetal tissue research has been critical in establishing permanent cell lines for use in vaccine research for diseases such as polio, hepatitis A, measles, mumps, rubella, chickenpox, and rabies. These established cell lines are currently being used to develop an Ebola vaccine.

Legislative proposals that halt research from cells already developed from fetal tissue and/or restrict scientists' access to new tissue or cell lines would have serious downstream consequences:

- They would limit new research on vaccines not yet developed, for treatments not yet discovered, for causes of diseases not yet understood.
- Some research questions cannot be answered using previous cell lines that have been immortalized; such proposals would prevent research that requires tissue that has been obtained more recently.
- Such proposals would restrict research only to organs or tissues for which cell lines currently exist, preventing new avenues of research exploring differences between tissue types.
- Such proposals would restrict access to new tissue necessary for the development and validation of novel research tools and technologies – essential to cutting-edge research.
- Organs and tissues are not just composed of a single type of cell, but rather an environment of multiple cell types; proposed restrictions would prevent scientists from studying the behavior of cells as they exist in our bodies.

As a prominent bioethicist has observed, the legal and ethical rules enforced for fetal tissue donation are similar in many respects to the ethics of organ donation. The ability to donate fetal tissue for medical research is not linked to an increase in the number of abortions practiced. Nor can we reasonably expect a limitation on fetal tissue donation or research to reduce the number of abortions. Rather, it will prevent the use of tissue that would otherwise be destroyed, hindering efforts to better understand, diagnose, and treat diseases.

We understand and share some of the concerns that have been raised in response to recent headlines, and our institutions endorse strong ethical practices that will address these concerns without shutting down vital research. We oppose any efforts to profit from the sale or distribution of human fetal tissue. Additionally, we embrace the best ethical practices that separate the decision to have an abortion from the decision to donate tissue for research.

As physicians and scientists, we work every day to save and improve lives. We urge lawmakers to support our ability to continue this important work by rejecting any proposals that restrict access to fetal tissue for research that has the potential to save countless lives.

American Association for the Advancement of Science
American Congress of Obstetricians and Gynecologists
American Physiological Society
American Society for Reproductive Medicine
American Society of Hematology
Association of American Universities
Association of Anatomy Cell Biology and Neurobiology Chairs
Association of Chairs of Departments of Physiology
Association of Medical School Microbiology and Immunology Chairs
Association of Public and Land-Grant Universities
Association of University Radiologists
Beth Israel Deaconess Medical Center
Boston Children's Hospital
Boston University School of Medicine
California Northstate University College of Medicine
Cedars-Sinai Medical Center
Children's Hospital Los Angeles
Columbia University Medical Center
Duke University School of Medicine
Feinberg School of Medicine, Northwestern University
Florida Atlantic University
Harvard University
Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo
Johns Hopkins University
Loma Linda University School of Medicine
Marshall University Joan C. Edwards School of Medicine
Medical College of Wisconsin
Michigan State University College of Human Medicine
Mount Sinai Health System
National Multiple Sclerosis Society
NYU Langone Medical Center
The Perelman School of Medicine at the University of Pennsylvania
Research!America
Roy J. and Lucille A. Carver College of Medicine at the University of Iowa
Rutgers Robert Wood Johnson Medical School
Stanford University School of Medicine
Stony Brook Medicine

SUNY Upstate Medical University College of Medicine
Temple University School of Medicine
Tufts University School of Medicine
Tulane University School of Medicine
Universidad Central del Caribe
University of Alabama School of Medicine
University of Chicago
University of Colorado School of Medicine
University of Illinois Hospital & Health Sciences System
University of Maryland, Baltimore
University of Massachusetts Medical School
University of Michigan Medical School
University of Nevada School of Medicine
University of New Mexico Health Science Center
University of Pittsburgh School of Medicine
University of Puerto Rico School of Medicine
University of Rochester Medical Center
University of Washington
University of Wisconsin-Madison
Virginia Commonwealth University School of Medicine
Washington University in St. Louis
Weill Cornell Medical College
Wright State University
Yale School of Medicine

NARAL
Pro-Choice America Foundation

Bioethics and Fetal Tissue: An Unfounded Attack on Reproductive Freedom

Testimony Presented by

Ilyse Hogue
President

U.S. House of Representatives
Energy and Commerce Committee
Select Investigative Panel

March 2, 2016

1156 15th Street, NW • Suite 700 • Washington, DC 20005
www.ProChoiceAmerica.org • 202 973 3000 • 202 973 3070 fax

Members of the Select Investigative Panel: I am honored to submit this testimony.

Today you are conducting a hearing on the topic of bioethics and fetal tissue. Research using fetal tissue is an important area of science that promises to help treat many conditions such as spinal cord injury,[1] cancer,[2] Parkinson's disease,[3] Alzheimer's,[4] neurological disorders,[5] and Down syndrome.[6] Some women who choose abortion also decide to donate the fetal tissue for research purposes – a practice that is well-regulated, and which has led to major medical breakthroughs. Current federal laws regarding fetal-tissue donation have as their primary concerns the protection of women, codification of the highest ethical standards, and assurance of humanitarian goals. NARAL Pro-Choice America supports and endorses these laws.

Despite this, for more than 20 years, opponents of reproductive rights have raised a series of alarmist, unproven claims about the practice of tissue donation. They have accused women, doctors, and researchers of systematically "trafficking" in "body parts," [7] and even more bizarrely, suggested that allowing tissue to be donated encourages abortion.[8] It is essential to note that these allegations have never been proved.

Today's hearing is yet another effort to advance these charges – in the hope that they will cast aspersions on scientists and their valuable work, shame women, stigmatize and terrify abortion providers, and ultimately, end legal abortion. NARAL Pro-Choice America opposes this attempt to exploit the ethical practice of fetal-tissue donation and to threaten women's reproductive choice.

This Hearing is Part of a Longstanding Effort to Attack Reproductive Freedom

Scientists have used fetal tissue in important research for decades – but in the 1980s, anti-abortion activists began mounting protests against it. Consequently, in 1988, the anti-choice George H.W. Bush administration imposed a moratorium on federal funding for the promising field of research.[9] Congress passed legislation overwhelmingly to lift the ban – a vote that included many prominent anti-choice lawmakers – but then-President Bush vetoed it.[10] Fetal-tissue research had been taken hostage by anti-abortion forces.

Upon taking office in 1993, newly elected pro-choice President Bill Clinton issued an executive memorandum lifting the moratorium.[11] Soon thereafter, Congress again passed legislation permitting and setting legal guidelines to govern fetal-tissue donation and research – and this time, the president (now Clinton) signed it.[12] That law remains in force today.

Anti-abortion forces mounted more attacks, however. In 1999, an anti-choice group called Life Dynamics circulated a letter on Capitol Hill charging that physicians were altering abortion procedures in order to obtain tissue appropriate for use in research.[13] Life Dynamics also claimed that the tissue was being sold for profit.[14] Founded in 1992, Life Dynamics is dedicated to using "guerilla" methods to make abortion unavailable by any means necessary, including threats, harassment, intimidation, and violence.[15]

Life Dynamics' allegations found a sympathetic ear among some anti-choice members of Congress: Rep. Tom Tancredo (R-CO) authored a resolution directing Congress to conduct a hearing on this alleged illegal profiteering.[16] The House passed the resolution by voice vote.[17] Sen. Bob Smith (R-NH) forced a floor vote on an amendment to other anti-choice legislation requiring any individual involved in research using fetal tissue to disclose sensitive information to the government - potentially exposing each to anti-choice harassment and violence.[18] (The Smith amendment failed, 46-51, opposed even by some anti-choice senators.[19])

Life Dynamics also publicized its allegations to the media. As a result, in 2000, the ABC television program *20/20* aired a segment on the topic, showing undercover footage of a tissue-procurement business owner, Dr. Miles Jones, boasting that he earned profit from the sale of donated fetal tissue.[20] Jones was subsequently cited for contempt of Congress, and upon learning of the tape, the pro-choice community contacted the Justice Department and urged an investigation.[21]

In a clearly coordinated effort, the anti-choice-led House Health and Environment Subcommittee held a hearing the day after the *20/20* report.[22] The only witness with allegations of impropriety, however, was thoroughly discredited under questioning from panel members, and was forced to admit that he had no direct knowledge of wrongdoing.[23] The witness, Dean Alberty, also admitted that he had done undercover work for the anti-choice group Life Dynamics while working as a tissue-retrieval technician.[24] The hearing concluded with no evidence of any widespread impropriety in the practice of fetal-tissue donation.

Despite the hearing's failure to uncover any wrongdoing, immediately following it, then-Rep. Tom Coburn (R-OK) and other anti-choice members of Congress introduced legislation mandating the public reporting of many of the same details Sen. Smith sought to publicize with his earlier bill.[25] The Coburn bill did not progress beyond introduction, but taken together, the various pieces of legislation show an eagerness on the part of anti-choice lawmakers to capitalize on sensational media reports (if not actual facts) to advance their overall agenda of rolling back reproductive freedom.

Another round of attacks following a similar progression began in 2015. Key individuals who previously were associated with the longstanding anti-choice organizations Live Action (which released a series of inflammatory tapes and made charges against Planned Parenthood in 2010 and 2011)[26] and Operation Rescue (an organization on the violent fringe of the anti-abortion movement)[27] reappeared on the scene: in July, an organization calling itself the "Center for Medical Progress" released a series of heavily edited videos claiming to show that Planned Parenthood health centers sell fetal tissue.[28] Planned Parenthood categorically denied the charges.[29] However, in yet another instance of apparent close coordination between advocates and elected officials, anti-choice politicians – in Congress and across states – responded instantaneously with a wide variety of legislative threats against reproductive rights and biomedical research.[30]

Interestingly, press outlets have reported that a number of anti-choice lawmakers admit having seen the "Center for Medical Progress'" footage several weeks previously but kept it quiet until the public reveal – only then declaring themselves outraged.[31] Today's hearing demonstrates that anti-choice forces are determined to continue these dangerous and unfounded attacks on reproductive freedom.

The Donation of Fetal Tissue for Research is a Legal and Ethical Practice

The most common charges made against fetal-tissue donation and research – specifically, that the practice encourages abortion and is unethical – are utterly unfounded.

Federal law ensures that a woman's decision to donate is made freely, with proper information, and free from conflicts of interest and explicitly prohibits profiteering in the sale of fetal tissue for research.[32] The NIH Revitalization Act of 1993 states that "[I]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration..."[33] Under this law, selling fetal tissue is a federal crime punishable by fines, imprisonment for up to 10 years, or both.[34] Similarly, the National Organ Transplant Act makes it unlawful for a person "to knowingly acquire, receive, or otherwise transfer any human organ," including fetal tissue, "for valuable consideration..."[35] This law also permits the reimbursement for certain expenses related to fetal-tissue donation (transportation, storage, preservation, etc.), just as it does for organ donation.[36]

Fetal tissue would be discarded if it were not donated, and legal guidelines require that a woman's decision to terminate a pregnancy is made first – and totally separately – from that of whether to donate tissue.[37]

When asked to review the appropriateness of research using fetal tissue, a National Institutes of Health panel recommended allowing such research, as long as sufficient protections for women and against conflicts of interest were enacted.[38] (Their recommendations were written into the federal law that now governs research with fetal tissue.) The Institute of Medicine and National Academy of Sciences have also examined the issue and concluded similarly.[39]

As bioethicist John Robertson argues: "In sum, fetal tissue transplants are practically and morally separate from decisions to end unwanted pregnancy."[40] Further, Robertson says, "The disparate issues ... can be treated separately, so that ethical concerns and the politics of abortion do not impede the progress of important research."[41]

Research Using Fetal Tissue is an Important Area of Science

Due to their capacity to divide rapidly, grow, and adapt to new environments, fetal cells hold unique promise for medical research. Research using fetal tissue has yielded significant advancements in the treatment of numerous diseases and medical conditions, including the

development of polio and rubella vaccines.[42] If not over-regulated or threatened out of existence, research with fetal tissue promises to help treat many conditions such as diabetes,[43] sickle cell anemia,[44] leukemia,[45] Huntington's,[46] stroke,[47] degenerative eye conditions,[48] radiation poisoning,[49] and others.[50]

It is instructive that those protesting against fetal-tissue donation are not similarly investigating – or expressing outrage about – organ donation. Human organs may also be donated legally, of course – in fact, the practice is widely encouraged and acknowledged as compassionate and ethical. And federal law allows reimbursement to doctors and health-care facilities for reasonable costs associated with that process.[51] Yet there have been no anti-choice objections to this practice.

Nor are the self-proclaimed opponents of fetal-tissue research calling for vaccines or treatments that have been discovered thanks to the use of fetal tissue to be pulled off the market and denied to all patients. Were they genuinely concerned that the practice of fetal-tissue donation actually encourages abortion, then demanding a recall of related vaccines and cures would be ethically consistent – extreme though it may be. The fact that they are instead calling to defund Planned Parenthood and to impose abortion bans on women speaks volumes about whether hearings like today's are truly concerned with medical ethics or are instead simply trumping up allegations in the service the goal of limiting women's reproductive choices.

Conclusion

Attacking fetal-tissue donations is part of a broader, calculated strategy. If individual cases of wrongdoing are discovered within the process of fetal-tissue donation, they should be investigated and, if appropriate, prosecuted. This is true of any kind of activity regulated by law; a different standard should not be applied to research that anti-choice advocates have systematically and deliberately politicized. As such, NARAL Pro-Choice America opposes this panel's attempt to inflame the debate around the ethical and legal practice of fetal-tissue donation and encourages lawmakers to defend against the threats it poses to reproductive freedom and scientific progress.

---

[1] Warren E. Leary, *Fetal Tissue Injected Into Injured Spinal Cord*, THE NEW YORK TIMES, July 12, 1997 *at* http://www.nytimes.com/1997/07/12/us/fetal-tissue-injected-into-injured-spinal-cord.html (last visited July 28, 2015); Sally Squires, *Spinal Cord Repair Research Yields Results*, THE WASHINGTON POST; Sept. 22, 1992, at Z06.

[2] *Fetal Tissue: Is It Being Sold in Violation of Federal Law?: Hearing before the House Subcomm. on Health and Environment*, 106th Cong. (2000) (testimony of Samuel M. Cohen, M.D., Ph.D., Professor and Chairman, Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska) (testimony of Joan I. Samuelson, J.D., President, Parkinson's Action Network); David Wahlberg, *Bill Floated to Ban Use of Aborted Fetal Tissue in Scientific Research*, WISCONSIN STATE JOURNAL, Apr. 10, 2013 *at*

http://host.madison.com/news/local/govt-and-politics/bill-floated-to-ban-use-of-aborted-fetal-tissue-in/article_5ba4f816-a175-11e2-88a1-0019bb2963f4.html (last visited July 23, 2015).

[3] Press Release, The White House Office of Communications, *We Must Free Science and Medicine from the Grasp of Politics*, (Jan. 22, 1993); *Fetal Tissue: Is It Being Sold in Violation of Federal Law?: Hearing before the House Subcomm. on Health and Environment*, 106th Cong. (2000) (testimony of Samuel M. Cohen, M.D., Ph.D., Professor and Chairman, Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska) (testimony of Joan I. Samuelson, J.D., President, Parkinson's Action Network).

[4] Press Release, The White House Office of Communications, *We Must Free Science and Medicine from the Grasp of Politics*, (Jan. 22, 1993); *Fetal Tissue: Is It Being Sold in Violation of Federal Law?: Hearing before the House Subcomm. on Health and Environment*, 106th Cong. (2000) (testimony of Samuel M. Cohen, M.D., Ph.D., Professor and Chairman, Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, Nebraska) (testimony of Joan I. Samuelson, J.D., President, Parkinson's Action Network).

[5] Conference Committee on Fetal Research and Applications, Division of Health Promotion and Disease Prevention, Institute of Medicine, *Fetal Research and Applications: A Conference Summary* (Washington, D.C.: National Academy Press, 1994), 7.

[6] Nikki Melina Constantine Bell, *Regulating Transfer and Use of Fetal Tissue in Transplantation Procedures: The Ethical Dimensions*, 20 AM. J.L. & MED. 277, 278 (1994).

[7] Phyllis Schlafly, *Human Chop Shops Exposed*, EAGLE FORUM, Mar. 15, 2000, *at* http://www.eagleforum.org/column/2000/mar00/00-03-15.html (last visited July 27, 2015).

[8] Julie Rovner, *Vote to End Fetal Tissue Ban Hinged on Personal Stakes*, CQ WEEKLY ONLINE, Apr. 4, 1992, *at* http://www.cq.com/doc/weeklyreport-WR102406478?12&search=0ZpDXFVO (last visited July 27, 2015).

[9] U.S. Department of Health and Human Services, National Institutes of Health, *Moratorium on Certain Fetal Tissue Research*, 17 NIH GUIDE FOR GRANTS AND CONTRACTS (Special Notice, May 9, 1988).

[10] National Institutes of Health Revitalization Amendments of 1991, H.R.2507, 102nd Cong. (as passed by Senate, Apr. 2, 1992); National Institutes of Health Revitalization Amendments of 1991, H.R.2507, 102nd Cong. (as passed by House, July 25, 1991); Veto Message from President George H.W. Bush to the House of Representatives, Returning Without Approval the National Institutes of Health Revitalization Amendments of 1992 (June 23, 1992), *at* http://www.presidency.ucsb.edu/ws/?pid=21134 (last visited July 27, 2015).

[11] Memorandum from William J. Clinton to the Secretary of Health and Human Services, Federal Funding of Fetal Tissue Transplantation Research, 58 FR 7457 (Jan. 22, 1993), codified at 42 U.S.C.A. § 289g.

[12] The National Institutes of Health Revitalization Act, 42 U.S.C.A. § 289g.

[13] The letter circulated by Life Dynamics was written by J.C. Willke, M.D., the President of Life Issues Institute, Inc., an organization dedicated to "serving the educational needs of the pro-life movement." Letter from John C. Willke, President, Life Issues Institute, Inc., to Honorable Nita M. Lowey, United States House of Representatives, June 25, 1999.

[14] Letter from John C. Willke, President, Life Issues Institute, Inc., to Honorable Nita M. Lowey, United States House of Representatives, June 25, 1999.

[15] *MDs Receive Antiabortion Mail*, THE GLOBE AND MAIL, Mar. 3, 1999, *at* https://advance.lexis.com/api/permalink/ac4d78b7-dc59-4723-afc6-5efae0fc502d/?context=1000516 (last visited July 28, 2015); Annetta Ramsay, *Texas Anti-Abortion Antics Go Back a Long Way*, WOMEN'S ENEWS, July 16, 2015 *at* http://womensenews.org/story/abortion/150715/texas-anti-abortion-antics-go-back-long-way (last visited July 30, 2015).

[16] H.R.350, 106th Cong. (Nov. 1999).

[17] H.R.350, 106th Cong. (as passed by House, Nov. 9, 1999).
[18] 145 Cong. Rec. S13025 (daily ed. Oct. 21, 1999), S.Amdt. 2324 to S.1692 A Bill to Ban Partial Birth Abortions.
[19] S.Amdt. 2324 to S.1692 A Bill to Ban Partial Birth Abortions, 106th Cong. (failed in Senate, Oct. 21, 1999).
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[51] National Organ Transplant Act, 42 U.S.C.A. § 274f.

EXHIBIT A-1

From: [redacted]
Subject: Updated Task Assignment: Procurement Schedule Wednesday 3/20/13
Date: March 20, 2013 at 9:00 AM
To: [redacted]

The following task has been updated on the [redacted] web office site.

TASK NAME: Procurement Schedule Wednesday 3/20/13
ASSIGNED BY: [redacted]
PROJECT: Procurement Schedule
CATEGORY: Procurement Schedule
PRIORITY: 2-Normal
STATUS: 1-Not Started
ASSIGNED TO: [redacted]
VISIBLE TO: Everyone

DETAILS:
Liver & Thymus (same donor)/16-20wks/RPMI/Wet Ice/HIV,HBSAG,HCV,CMV/FedEx Priority Overnight/Mass General Hospital ([redacted])
1 SPEC=
IMPORTANT: Please document PO#0005446200 in the reference section

Liver & Thymus (Same donor)/16-20wks/RPMI /Wet Ice/ HIV,HBsAG,HCV/FedEx Priority Overnight/UMASS ([redacted])
1 SPEC=
IMPORTANT: Please document PO#0006147108 in the reference section.

Liver/18-22wks/RPMI/Wet Ice/FedEx Priority Overnight/ UCLA ([redacted])
IMPORTANT: Please document PO#1559NQA55800 in the reference section.
2 SPEC=
This used to be researcher- UCLA: [redacted]

Liver, Thymus & Skin (Same donor)/16-20wks/RPMI /Wet Ice/ HIV,HBsAG,HCV/FedEx Priority Overnight/HARVARD ([redacted])
1 SPEC=
IMPORTANT: Use FedEx account #431793989. Note: THE LIVER AND THYMUS SHIP TO [redacted] AT UMASS AND THE SKIN SHIPS TO [redacted] AT HARVARD. SHIP ALL TISSUE UNDER HARVARD'S FEDEX NUMBER.
**[redacted] Research Specialist Melton Group, HHMI/Harvard Dept of Stem Cell and Regenerative Biology, 7 Divinity Avenue-Fairchild 360, Cambridge, MA 02138, email-[redacted] Phone: [redacted].

PROCURE ON WEDNESDAY ONLY- Pancreas/14wks/HEPES with antibiotic/Gel Pack/HIV, HBSAG, HCV/FedEx Priority Overnight/UMASS ([redacted])
2 SPEC=
IMPORTANT: Use gel packs that are NOT frozen but just chilled.
IMPORTANT: Please document PO#0006147108 in the reference section.

Brain /16-18wks/Complete but can be in piecest/Use Client Supplied Media/Wet Ice/HIV,HBsAG,HCV/Use Clients FedEx Priority Overnight/Temple Univ ([redacted])

1 SPEC=
Note: Media contains anti-fungal/anti-mycotic and antibiotics
Researcher: [redacted]

Mid Brain/10+wks/RPMI/Wet Ice//HIV, HBSAG/FedEx Priority Overnight/University of Illinois at Chicago (Qu-Yang)
1 SPEC=
Researcher: [redacted] or [redacted]

Brain/14+wks (2cm in width)/Whole brain In-tact or one whole Hemis intact/Dry

EXHIBIT A-2

[redacted]

Procurement Technician Compensation Policy for Tissue and Blood Procurement Effective 01/01/2013

Procurement Fees

- Procurement Technicians are compensated at a rate of $10.00 per hour plus a per tissue or blood bonus as outlined in the table below:

Tissue Bonus Structure			
# Specimens	Category A*	Category B*	Category C
1-10 Specimens	$35/Tissue	$15/Tissue	$10/Blood
11-20 Specimens	$45/Tissue	$20/Tissue	$15/Blood
21-30 Specimens	$55/Tissue	$25/Tissue	$20/Blood
31-40 Specimens	$65/Tissue	$30/Tissue	$25/Blood
41-50 Specimens	$75/Tissue	$35/Tissue	$30/Blood

*Blood Samples may be obtained with these specimens in which case Category C bonus does not apply.

Please refer to the Procurable Specimens by Category dated 01/01/2013 for a detailed listing of Tissues.

Two or More Procurement Technicians working in Unison

- Procurement Technicians often work in unison so procurements are split equality between the technicians.

For example, if two technicians are working together at the same clinic, and two maternal bloods are procured, each technician would receive $5 for the Blood Procurement.

[redacted]

EXHIBIT A-3

[redacted]

Client Information for Informed Consent

DONATION OF BLOOD AND/OR ABORTED PREGNANCY TISSUE FOR MEDICAL RESEARCH, EDUCATION, OR TREATMENT

Research using the blood from pregnant women and tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS. [redacted]

You can donate your blood and/or pregnancy tissue after an abortion. Before you give your consent, read each of the following statements and initial the line to the right. We will be happy to answer any questions you have.

Before I was shown this consent, I had already decided to have an abortion and signed a consent form for it. _____

I agree to give my blood and/or the tissue from the abortion as a gift to be used for education, research, or treatment. _____

I understand I have no control over who will get the donated blood and/or tissue or what it will be used for. _____

I have not been told the name of any person who might get my donation. _____

I understand there will be no changes to how or when my abortion is done in order to get my blood or the tissue. _____

I understand I will not be paid. _____

I understand that I don't have to give my blood or pregnancy tissue, and this will not affect my current or future care at [redacted] _____

Signature:_____ Date:_____

Witness:_____ Date:_____

[redacted]

[redacted]

[redacted]

[redacted]

EXHIBIT B-1

From: Redacted
Sent: Wednesday, January 21, 2015 3:19 PM
To:
Cc: Redacted
Subject: Re: PO# 60858758

Redacted

Thank you for letting me know. We are now ready to include the skull so if you could please include that in our order for tomorrow that would be great. Just to clarify we are happy to receive one or the other depending on damage/integrity. If there is a case tomorrow could you please have someone contact me with the condition of both the long bones and the calvarium and I will be happy to let you know if we would like one or both.

----- Original Message -----
From: Redacted
To:
Cc: Redacted
Sent: Wednesday, January 21, 2015 3:23:30 PM
Subject: RE: PO# 60858758

Redacted

I will be happy to do that.

Thank you,

Redacted

EXHIBIT B-2

Redacted

From: Redacted
Sent: Thursday, January 22, 2015 12:26 PM
To:
Cc: Redacted
Subject: Re: PO# 60858758

Hi Redacted

Just wanted to check in and see if there were any cases within our gestation range for today? Need to book some time on the equipment if so.

Thanks,

Redacted

Sent: Thursday, January 22, 2015 12:30:11 PM
Subject: RE: PO# 60858758

Hello,

There is one case currently in the room, I will let you know how the limbs and calvarium look to see if you are able to take them in about fifteen minutes.

Thank you,

From: Redacted
Sent: Thursday, January 22, 2015 12:33 PM
To: Redacted
Subject: Re: PO# 60858758

Great thank you so much.

----- Original Message -----
From: Redacted
To: Redacted
Cc: Redacted

EXHIBIT B-3

----- Original Message -----
From: Redacted
To:
Cc: Redacted
Sent: Thursday, January 22, 2015 1:02:32 PM
Subject: RE: PO# 60858758

Redacted

The Calvarium is mostly intact, with a tear up the back suture line, but all pieces look to be there.

The limbs, one upper and one lower are totally intact, with one upper broken at the humerus, and one lower broken right above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply.

Thank you,
Redacted

From: Redacted
Sent: Thursday, January 22, 2015 1:07 PM
To: Redacted
Subject: Re: PO# 60858758

Redacted

That sounds great we would like both of them.

Please send them our way,

Thanks again,

Redacted

Subject: RE: PO# 60858758

Redacted

Limbs and Calvarium will be there between 3:30 and 4:00.

Thank you,

Redacted

EXHIBIT C-1

DEPARTMENT OF HEALTH SERVICES
Division of Public Health
F-43025 (Rev.01/2016)

STATE OF WISCONSIN

DOCUMENT OF ANATOMICAL GIFT
AUTHORIZATION FOR ORGAN AND TISSUE DONATION

I / *You*, _____ give permission for
(Name of Authorizing Person)

the donation of anatomical gifts from _____
(Name of Donor)

to benefit humanity as set forth in this ***Document of Anatomical Gift***. This Document is being completed:

☐ In-person and witnessed
[ ] Copy of document provided

☐ Via telephone and recorded
[ ] Copy of document to be mailed.

If recorded, a copy of this conversation is available upon request.

I / *You* grant permission for the recovery of the following Organs and/or Tissues for purposes of:

Transplantation ☐ Yes ☐ No Research ☐ Yes ☐ No Education and Training ☐ Yes ☐ No:

ORGANS		TISSUES	
Heart	☐ Yes ☐ No ☐ N/A	Eyes	☐ Yes ☐ No ☐ N/A
Lungs	☐ Yes ☐ No ☐ N/A	Corneas	☐ Yes ☐ No ☐ N/A
Liver	☐ Yes ☐ No ☐ N/A	Heart for Valves/Pericardium	☐ Yes ☐ No ☐ N/A
Kidneys	☐ Yes ☐ No ☐ N/A	Blood Vessels (Arteries and Veins)	☐ Yes ☐ No ☐ N/A
Intestines	☐ Yes ☐ No ☐ N/A	Skin	☐ Yes ☐ No ☐ N/A
Pancreas or islet cell	☐ Yes ☐ No ☐ N/A	**BONE AND CONNECTIVE TISSUE OF:** (includes ligaments, tendons & supporting structures)	
		Upper Arm	☐ Yes ☐ No ☐ N/A
		Lower Arm	☐ Yes ☐ No ☐ N/A
		Lower Extremities	☐ Yes ☐ No ☐ N/A
		Pelvis	☐ Yes ☐ No ☐ N/A
		Ribs	☐ Yes ☐ No ☐ N/A
Other organ or tissue donation requests: ☐ None or Specify: _____			

I / *You* grant permission for:

- Any testing, examinations, and procedures that may be necessary to determine the medical eligibility of this gift. This includes, but is not limited to, testing for HIV and Hepatitis, removal of adjacent blood vessels for organ transplantation, collection of inguinal/abdominal lymph nodes and spleen, and the collection of blood and biopsy samples for potential recipient compatibility testing.
- The release of any information, including medical information found within sources to include, but not limited to, hospital records, death certificates, and postmortem examination (autopsy) reports, and information relating to HIV and Hepatitis to determine organ and tissue eligibility. This information may be released to other appropriate agencies.

I / *You* understand that:

- Expenses related to the evaluation, maintenance, recovery and placement of the organs and tissues will be paid by the recovery organization(s).
- Funeral and burial expenses are not the responsibility of the recovery organization(s).
- The donation process may take several hours to complete, and the release to the funeral home or coroner/medical examiner's office, when applicable, will occur after the recovery process has concluded.

Name of Donor | Date of Birth | ID Number

EXHIBIT C-2

I / *You* further understand that:

- I / *you* may, by this document, limit the use of the bones or tissues, including skin, that are donated or types of organizations that recover, process, or distribute the donation.
- Donated bones or tissues, including skin, may have numerous uses, including for reconstructive and cosmetic purposes, and multiple organizations, including nonprofit and for-profit organizations, may recover, process, or distribute the donations. In addition, recovered tissues may be distributed internationally.
- It may be necessary to transport the Donor to another location for the purpose of tissue recovery.
- I / *You* specify the following limitations on the use of bones or tissues or on the types of organizations that recover, process, or distribute the donation.

☐ None ☐ Specific limitations: _____

_____
Initials of Authorizing Person*

I / *You* have been given:

- The option to receive information about how donated organs and/or tissue were used.
- The opportunity to ask questions about the donation process
- An explanation of donation options in a language that I / *you* understand.

Having read this Document of Anatomical Gift in its entirety, or having had it read to me, I / *you* now give this authorization freely without expectation of any compensation:

Print Name of Authorizing person	**SIGNATURE** - Authorizing Person*	Date / Time Signed
Relationship to Donor		
Street Address	City, State, Zip	Telephone Number
Print Name of Witness	**SIGNATURE** – Witness*	Date / Time Signed
Print Name of Person completing this form	**SIGNATURE** - Person completing form	Date / Time Signed
Name of organization retaining taped consent		

**The person completing this form via telephone should initial the space above as appropriate.*

The following contact information is provided for use by the authorizing person(s):

☐ **University of Wisconsin OPO**
450 Science Drive, Suite 220
Madison, Wisconsin 53711-9135
Phone: (866) 894-2676

☐ **Lions Eye Bank of Wisconsin**
2401 American Lane
Madison, WI 53704
Phone: (877) 233-2354

☐ **BloodCenter of Wisconsin/ Wisconsin Donor Network - OPO**
638 North 18th Street
Milwaukee, WI 53233
Phone: (800) 722-8230

☐ **American Tissue Services Foundation**
5940 Seminole Centre Court, Suite #210
Madison, WI 53711
Phone: 888-560-6001

☐ **RTI Donor Services**
8120 Forsythia St. Suite 2
Middleton, WI. 53562
Phone: (877) 733-3700

☐ **BloodCenter of Wisconsin/ Wisconsin Tissue Bank**
638 North 18th Street
Milwaukee, WI 53233
Phone: (800) 722-8230

Name of Donor | Date of Birth | ID Number

EXHIBIT D

harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitle.

EXHIBIT E

[redacted]

From: [redacted]
Sent: Tuesday, February 23, 2016 1:33 PM
To: [redacted]
Subject: Fwd: question about tissue

---------- Forwarded message ----------
From: [redacted]
Date: Tue, Jul 15, 2014 at 8:18 PM
Subject: Fwd: question about tissue
To: [redacted]

Hi Everyone,

Here is the response I got from [redacted] at [redacted] about their procurement procedure:

Once the surgery is completed, the tissue it brought to the 'lab' area. Not really a lab, no hood..just where the tissue is taken. After it gets to the lab and the doctor determines that the procedure is complete, the [redacted] tech is allowed to begin procurement. This takes a couple of minutes. When the tissue is procured, it is put into cooled RPMI and either placed in a refrigerator or in a cooler (with ice packs) while the paperwork is being completed. Once the paperwork is completed, the tissue is put into the transport container containing wet ice, and shipped via FedEx to its destination.

The elapsed time from the surgery being completed to the tissue being put into the cooler/refrigerator is less than 10 minutes.

[redacted]

EXHIBIT F

> ---------- Forwarded message ----------
> From: [redacted]
> Date: Apr 17, 2014 5:26 PM
> Subject: tissue request
> To: [redacted]
> Cc:
>
> Hello,
>
> Dr. [redacted] at the University of [redacted] would like to request a
> first
> trimester human embryo, preferably around 8 weeks, and up to 10 weeks
> gestation. We have ordered tissue from [redacted] before, so our information
> should be on file. Please let me know if this tissue is available.
>
> Thanks,
> [redacted]
>

EXHIBIT G

APPENDIX B

Model Elements of Informed Consent for Organ and Tissue Donation

American Association of Tissue Banks
Association of Organ Procurement Organizations
Eye Bank Association of America

Human organ and tissue transplantation has become an important and growing part of modern medical practice. Advances in medical science have made it possible for millions of Americans to receive these life-saving and life-enhancing gifts. None of this would be possible, however, were it not for the tens of thousands of donors and donor families who give their organs and tissues to help their fellow men and women.

The decision to donate must, therefore, be an informed consent, and it must be conducted under circumstances that are sensitive to the consenting person's situation. Information concerning the donation should be presented in language and in terms that are easily understood by the consenting person. The consent should be obtained under circumstances that provide an opportunity to ask questions and receive informative responses. An offer should be made regarding the availability of a copy of the signed consent form, and information should be provided regarding ways to reach the recovery organization following donation. Consent should be obtained in accordance with federal, state and/or local laws and/or regulations. The person seeking the consent should be trained to appropriately answer any questions that the consenting person may have. In addition, coercion should not be exerted in any manner, nor monetary inducement offered to obtain consent for donation. The identification of who may be the appropriate person to consent to donation, and whether the consent of any person in addition to the donor needs be obtained, should be evaluated in accordance with the applicable laws and organizational policy and is not addressed in this statement.

The following list of "Basic Elements of Informed Consent" is intended to highlight the information that may be considered critical to informed decision making by a family member or other legally authorized person, who is being approached for consent to organ and/or tissue donation. This listing, whether communicated verbally or included on consent forms, is not intended to preempt any applicable federal, state, or local laws or regulations that may require more or less information to be disclosed for informed consent to be legally effective.

Basic Elements of Informed Consent

In seeking informed consent, the following information should be provided to the person(s) being approached for consent:

- A confirmation/validation of the donor's identity and his or her clinical terminal condition.
- A general description of the purposes (benefits) of donation.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

March 23, 2016

Dr. G. Kevin Donovan
Director, Pellegrino Center for Clinical Bioethics
Georgetown University Medical Center
4000 Reservoir Road, N.W.; Suite 120
Washington, DC 20007

Dear Dr. Donovan:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, March 2, 2016, to testify at the hearing entitled "Bioethics and Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, April 6, 2016. Your responses should be mailed to Rachel Collins, Investigative Counsel and Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Rachel.Collins@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: The Honorable Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

Questions for the Record for Dr. Kevin Donovan –

1. At the hearing, the claim was made that without fetal tissue, Zika virus research could not go forward. Only days later, the Washington Post cited a Cell Stem Cell research project in which induced pluripotent stem cells were engineered to study the characteristics of the virus's infectious potential in developing neural tissue. Since the breakthrough study produced vital information, why the insistence that fetal tissue is required to develop a vaccine or to study the infection's progress?

This does not get at the ***motivation*** for the insistence on fetal tissue, but gives you more background on the licit alternatives. The insistence seems to be motivated from a desire to continue the same research and cell sources (i.e., tradition, what's worked in the past), resistance to change (it might delay experiments), and likely an ideological undertone (failure to recognize the basis of the controversy, or to give any credence or consideration to alternative ethical viewpoints.)

While the earliest attempts at growing viruses did use cultures of unpurified human fetal tissue, most research, as well as vaccine production, quickly shifted to purified cell lines, which lent themselves to considerably less variability and provided large numbers of quality-controlled cells, providing reproducible results. In the 1960's and 1970's, cell culture work operated under an assumption that younger cells grew better, faster, and longer, so fetal cells obtained from abortion were sometimes used to create these cell lines (indicating they were developed as a lineage from a specific, original source of cells grown in the lab. A few human fetal cell lines (WI-38, MRC-5) are still in use for some vaccine production. However, few vaccines are now produced using fetal cell lines, and none using fetal tissue. Newer cell lines, e.g., A549 cells (adult human),[1] Sf9 cells (insect),[2] EB66 (duck),[3] and better culture techniques make reliance on fetal cells an antiquated science. In addition, the CDC and other leading medical authorities have noted since 2001 that "No new fetal tissue is needed to produce cell lines to make these vaccines, now or in the future."[4]

The example referenced in the question is another clear answer for the lack of need for freshly aborted fetal tissue in virus and vaccine studies. Scientists developed a successful model system to show that the Zika virus can infect and damage some developing brain cells.[5] The established experimental model, which the authors of the paper note can now be used for further investigations of developing brain as well as screening therapeutic compounds, was not developed using fetal tissue. The successful system uses human induced pluripotent stem cells (iPS cells), which are ethically created from skin or other

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[1] See e.g., Shabram P and Kolman JL, Evaluation of A549 as a New Vaccine Cell Substrate: Digging Deeper with Massively Parallel Sequencing, *PDA J Pharm Sci Technol* 68, 639, 2014

[2] See e.g., Glenn GM et al., Safety and immunogenicity of a Sf9 insect cell-derived respiratory syncytial virus fusion protein nanoparticle vaccine, *Vaccine* 31, 524, 2013; AND Khan AS, FDA Memo: Cell Substrate Review for STN 125285, January 14, 2013; accessed at:
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM339125.pdf

[3] See e.g., Brown SW, Mehtali M, The Avian EB66(R) Cell Line, Application to Vaccines, and Therapeutic Protein Production, *PDA J Pharm Sci Technol*. 64, 419, 2010

[4] See, *e.g.*, "Vaccine Ingredients – Fetal Tissues," The Children's Hospital of Philadelphia, 2014; accessed July 21, 2015 at www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients/fetal-tissues; CDC quote originally accessed July 2015 at: http://www.ascb.org/newsfiles/fetaltissue.pdf

[5] Tang H *et al.*, Zika Virus Infects Human Cortical Neural Progenitors and Attenuates Their Growth, *Cell Stem Cell* 18, 2016; *in press*, doi: 10.1016/j.stem.2016.02.016

normal cell types; the development of iPS cells earned the 2012 Nobel Prize for Dr. Shinya Yamanaka of Japan.

Another recent study by a Brazilian group confirmed the susceptibility of developing human brain cells to Zika virus infection, with potential damage to infected brain cells. Again, the successful study did not use human fetal tissue, but rather human iPS cells.[6]

Human iPS cells have demonstrated excellent potential to model developing brain, producing what are termed "organoids" for detailed study of the various cell types, brain structures, and even abnormal development that can occur. In particular, one model system using human iPS cells to produce brain organoids has been shown also to be an accurate model to study Microcephaly, the brain development condition that seems to be associated with infection by Zika virus in the womb.[7] And a newly-published paper further validates the superior ability of human iPS cells to model brain development. While this new reference does discuss Zika in particular, it convincingly demonstrates that this model system for brain development – which does not use aborted human fetal tissue – can be used to model normal human brain development, the timing of brain development associated with production of various neuronal cell types, and even to compare human brain development versus that of monkeys.[8]

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[6] Garcez PP *et al.*, Zika virus impairs growth in human neurospheres and brain organoids, *PeerJ Preprints* 4:e1817v3; doi: 10.7287/peerj.preprints.1817v3

[7] Lancaster MA *et al.*, Cerebral organoids model human brain development and microcephaly, *Nature* 501, 373, 19 Sept 2013

[8] Otani T *et al.*, 2D and 3D Stem Cell Models of Primate Cortical Development Identify Species-Specific Differences in Progenitor Behavior Contributing to Brain Size, *Cell Stem Cell* published online March 31, 2016, doi: 10.1016/j.stem.2016.03.003

2. You testified that "it does exist and it is more ethical" in response to a question about the existence of alternative sources of tissue to form fetal cell lines, "such as spontaneous miscarriages."
Please expand your testimony to include other alternative sources of tissue that you are aware of which may be used to form fetal cell lines and that you believe to be ethical.

Those opposed to using fetal tissue from miscarriages argue that an insufficient amount of suitable tissue would be available for certain studies, such as transplantation. Several papers published by Dr. Maria Michejda at Georgetown University School of Medicine outline very clearly that spontaneous miscarriages are a useful and ethical alternative source of fetal stem cells for hematopoietic cell transplantation (for review see Michejda, 2002, 2004), and other labs have agreed with her findings (Low et al, 1994; Wu et al., 1999). An additional report characterized 12 and 18 week old fetuses from spontaneous abortions and was able to study key cells involved in brain development (Virgintino et al., 1998). Another study was recently conducted using fetal tissues from both induced and spontaneous abortions, side-by-side (Kang et al., 2016).
Other arguments against the use of fetal tissue from miscarriages include the unknown time of death and possible genetic abnormalities. In regard to timing, numerous reports, together with Dr. Michejda's epidemiological studies, have indicated that over 15% of the 300,000 second-trimester miscarriages studied were suitable for transplantation (which has some of the most rigorous requirements for tissue viability), when collected and preserved properly (Michejda, 2002). In response to genetic concerns, a fetus can appear "normal" until an inherent genetic abnormality manifests itself after birth. In fact, birth defects are the leading cause of infant deaths, accounting for 20% of all infant deaths (Matthews et al., 2015). So like miscarriages, fetal tissue from induced abortions can also carry genetic abnormalities. In addition, the use of the abortion drug, mifepristone (RU-486), and prostaglandins for the medical termination of pregnancy may substantially reduce the availability of human fetal tissues from induced abortions (Branch et al., 1995). Furthermore, if there are concerns that tissues from miscarriages are not "normal", comprehensive screening tools are available and can be used to identify relevant genetic abnormalities.

Branch, D.W., et al. Suitability of fetal tissue from spontaneous abortions and from eetopic pregnancies for transplantation. JAMA, 273:66, 1995
Kang, X., et al., Granulocytic myeloid-derived suppressor cells maintain feto-maternal tolerance by inducing Foxp3 in CD4+CD25-T cells by activation of the TGF-b/b-catenin pathway. Mol Hum Reprod, 2016 [Epub ahead of print]
Low, W.C., et al., Human fetal tissue from spontaneous abortion as potential sources of donor tissue for cell transplantation therapies. Transplantation Proceedings, 26:1, 1994
Matthews, T.J., et al., Infant mortality statistics from the 2013 period linked birth/infant death data set. Center for Disease Control and Prevention, National Vital Statistics Reports, 64 (9):1, 2015.
Michejda, M., Spontaneous miscarriages as a source of fetal stem cells. The national catholic bioethics quarterly, 2:401, 2002
Michejda, M., Which stem cells should be used for transplantation? Fetal diagnosis and therapy, 19:2, 2004
Virgintino, D., et al., Astroglia-microvessel relationship in the developing human telencephalon. Int. J. Dev. Biol., 42:1165, 1998
Wu, A.G., et al. Analysis and characterization of hematopoietic progenitor cells from fetal bone marrow, adult bone marrow, peripheral blood, and cord blood. Pediatric Research, 46:163, 1999

3. **Why is it necessary to have different ethical guidelines governing consent to donate fetal tissue for minors as opposed to adults? Further, how might a minor be unduly influenced to donate fetal tissue if presented with the consent form, such as Exhibit A-3?**

Informed consent cannot take place unless the patient has decision-making capacity. This requires three distinct aspects:

A) Comprehension, or the ability to understand. This would include the ability to appreciate the impact and consequences of procedures donations etc.

B) The ability to evaluate or deliberate in accordance with one's own values. This presupposes the ability to compare risks and benefits of the options and to make rational choices that are consistent over time.

C) Communication, and absence of coercion.

The obvious problem is that minors have poorly developed decision-making capacity, due to immature value systems, poor appreciation of possible consequences, and particularly in this situation, undue influence of the situation and environment in which they find themselves. In fact, any negative responses might make them feel they are jeopardizing their chances of going forward with the planned abortive procedure, thus impairing the truly free exercise of their will, i.e. they feel "they have no choice". This is why minors are not free consent to medical and surgical procedures under normal circumstances, without parental permission.

Moreover, truly valid informed consent requires adequate and honest disclosure of information. To be presented with a document such as Exhibit A – 3 would be highly misleading. It states, "Research using the blood from pregnant women and tissue that has been aborted has been used to ***treat and find a cure*** (emphasis added) for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS." As any well-informed adult knows, there have been no successful cures developed for any of the stated diseases, with or without the use of aborted fetal tissue, and no treatments that are based on fetal body parts. This is a flagrant misrepresentation, creating an undue and therefore coercive incentive, and should not appear in any legally or ethically approved consent form.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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Majority (202) 225-2927
Minority (202) 225-3641

March 23, 2016

Ms. Paige Comstock Cunningham
Executive Director
The Center for Bioethics and Human Dignity
Trinity International University
2065 Half Day Road
Deerfield, IL 60015

Dear Ms. Cunningham:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, March 2, 2016, to testify at the hearing entitled "Bioethics and Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: The Honorable Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

Cunningham, Paige Comstock
April 6, 2016
Responses to Additional Questions for the Record from Chairman Blackburn

1. **In response to a question about "obtaining embryos on demand" (referencing Exhibit F), you testified that "my concern is that researchers have come to count on induced abortions for their research."**

Please elaborate on what alternatives to fetal tissue from induced abortion that are available to researchers.

As I am neither a scientific or medical researcher, I am not qualified to respond to the availability of alternative sources. As a lawyer and bioethicist, I am aware of reports of successes in using ethical tissue sources, such as adult stem cells and induced pluripotent stem cells (iPSCs), to treat a broad range of diseases. Their availability and value would seem to be reflected in the allocation of public funds for research using these alternatives, including funding previously directed to embryo stem cell research.[1]

It may be that using ethical alternatives requires greater patience. Even if developing therapies for diseases takes longer, alternatives to fetal tissue must be employed. This is ethically preferable; I would argue that it is ethically mandated. These diseases have existed for centuries. Just because new techniques are available does not warrant unethical shortcuts in order to trim a few months or years from developing a therapy, if the cost is the destruction of presently existing human beings for the sake of unidentified future human beings.

Also, are there other steps that could be taken to reduce researchers demand for fetal tissue from induced abortions without jeopardizing research?

Again, I am not qualified to respond to researchers' demand for fetal tissue. However, I would note the obvious: demand for fetal tissue, and the reliance on its availability, exists because of the widespread practice of abortion. Were fetal remains not widely available, other avenues would be devised. In fact, recent research on vaccines or treatments for diseases which have garnered global public attention, such as the Ebola and Zika viruses, does not rely on fetal tissue.[2]

2. In response to a question about whether a series of emails (Exhibits B1-Be) raised any ethical concern, you testified that "it completely fails to isolate abortion from the decision about the fetal tissue and consent to use the fetal tissue" and that there was "no indication of consent prior to this procedure or for these specific parts to be excised."

What ethical concerns arise when there is a failure to isolate an abortion procedure from the patient consent obtained for fetal tissue donation prior to an abortion being performed?

The moral harm of abortion cannot be undone by donating the fetal remains for research. Nor can the mechanism of procuring the specific fetal body parts requested be separated from the abortion procedure. Research that relies on induced abortion is not simply a matter of using material that is available. An entire industry has grown up around the practice of abortion, to the extent that institutions routinely submit purchase orders not only for entire fetuses, but also for specific body parts. Ordering specific parts treats the fetus as a product to be dissected piecemeal, and the woman as a convenient incubator.[3] The purchase orders referenced in Exhibit A-1 indicate that a single fetus may be parsed among at least two institutions.

Separation of consent to abortion and consent to donation. Federal law makes clear that the woman's consent to donate fetal remains for research must be solicited separately from, and subsequent to, her decision to abort.[4] One of the reasons for this dividing line between the abortion decision and the donation decision is to ensure that a woman not be induced to obtain an abortion because of the possibility that "some good might come out of it." Whether or not donation is a significant inducement, it is a significant ethical consideration.

In the case of cadaveric organ donation, the discussion with the patient's family, and their decision about, continuation of life-sustaining treatment must be separated from discussion about organ donation. The same personnel should not conduct or even participate in both discussions, creating clear lines between when and where each informed consent conversation takes place, and who is involved.[5] In part, this ensures that the patient's best interests are protected. Also, it minimizes the possibility that a compelling organ procurement officer might induce the family to consent to donation and removal of life-sustaining treatment they otherwise would have continued. The Office of Inspector General of the Department of Health and Human Services notes that "Families are asked to give their consent at a point in time when they are extremely vulnerable."[6]

Preying upon the woman's vulnerability. In the abortion context, discussion about donation of fetal remains that is close in time, location, and with the same person, may unduly pressure a woman who is not only vulnerable, but may be ambivalent about the upcoming abortion. The stress of any surgery may make it difficult to process the long-term implications of an immediate decision, let alone future regrets or satisfaction. Contemplating an abortion is a stressful event. The UK Human Tissue Authority (HTA) writes that, "the loss or termination of a pregnancy, whatever the circumstances, is clearly an exceptionally sensitive and emotional time for a woman."[7] The HTA further notes that even if she does decide how to dispose of "pregnancy remains," she "may change her mind at a later date or ask about what arrangements were made."[8]

Time consuming process. As the Department of Health and Human Services makes clear, "informed consent is a process, not just a form."[9] Those who have years of experience with

cadaveric organ donation for transplant can attest that an adequate consent process is time-consuming, involving more than a perfunctory inquiry and a signature on a document.

Inadequacy of consent. The consent form presented at the hearing on "Bioethics and Fetal Tissue"[10] is grossly deficient. It misrepresents the state of fetal tissue research, alleging that through such research cures have been found for "such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS." A woman reading this statement might be induced to donate because she believes that her child's tissue might be used to "cure cancer."

If she were given fully informed consent, she might even change her mind about proceeding with the abortion. Specific elements of fully informed consent include how the tissue will be stored; notification if the tissue is deemed unusable; whether the tissue will be used outside the US; whether the tissue will be modified (e.g., into commercial products); receipt of a copy of the informed consent document; and, the morally relevant distinctions between the 'for profit' and 'nonprofit' organizations involved.[11] The schedule of graduated "bonus" payments to procurement technicians procuring a greater number of specimens[12] is a glaring ethical violation. It points toward a profit motivation in obtaining the woman's consent, particularly if the technician is the person designated to obtain consent. Her refusal to consent translates into reduced income for the technician.

Outside the abortion context, consent forms itemize the specific organs and tissues being donated. It should be no different for abortion: the specific body parts that will be harvested, whether a brain, spinal cord, liver, thymus, or lungs. This information is relevant, and might even give her pause about her abortion decision. The risk of "humanizing" the human fetus is no excuse for shoddy practices.

Separation of abortion procedure from request to harvest specific tissues. Further, there must be "no alteration of the timing, method, or procedure used to terminate the pregnancy solely for the purposes of obtaining the tissue."[13] Although the Exhibit A-3 consent form states that there will be "no changes to how or when my abortion is done," there must be independent corroboration of this statement. The woman's consent to the abortion and her separate consent for donation should be not only signed and dated, but also time stamped, and her medical records should note the same. The scheduling and method of abortion procedure should be noted in her records *prior* to any discussion of possible donation of fetal remains.

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[1] See, e.g., David A. Prentice, "Midwest Stem Cell Therapy Center – Kansas' Unique Initiative," Kansas Senate Ways and Means Committee, Senate Public Health and Welfare Committee, House Appropriations Committee, and House Health and Human Services Committee, February 8, 2016. Accessed online on April 7, 2016, at https://lozierinstitute.org/wp-content/uploads/2016/02/Prentice-KS-Senate-House-MSCTC-update-8Feb2016.pdf.

[2] See, e.g., Agnandji ST et al., "Phase 1 Trials of rVSV Ebola Vaccine in Africa and Europe — Preliminary Report," *New England Journal of Medicine,* published on April 1, 2015; doi: 10.1056/NEJMoa1502924; originally developed by the Public Health Agency of Canada, which patented it in 2003, http://www.google.com/patents/WO2004011488A2?cl=en (using a monkey cell line).

See also, Tang H *et al.*, Zika Virus Infects Human Cortical Neural Progenitors and Attenuates Their Growth, *Cell Stem Cell* 18, 2016; *in press,* doi: 10.1016/j.stem.2016.02.016 (using human induced pluripotent stem cells (iPSCs). Accessed online April 7, 2016 at http://www.cell.com/cell-stem-cell/abstract/S1934-5909(16)00106-5.

[3] See Exhibit B-2, where emails sent during the procedure discuss the availability and condition of specific body parts (calvarium and limbs).

[4] 42 U.S.C. §289g-1 (2010).

[5] See, e.g., "Ethical Controversies in Donation after Cardiac Death," Policy Statement, American Academy of Pediatrics, *Pediatrics* 131, no. 5 (2015): 1021-1028. Available at http://pediatrics.aappublications.org/content/pediatrics/131/5/1021.full.pdf.

[6] U.S. Department of Health and Human Services "Informed Consent in Tissue Donation: Expectations and Realities" prepared by the Office of Inspector General, January 2001, 6.

[7] Human Tissue Authority, "Guidance on the Disposal of Pregnancy Remains Following Pregnancy Loss or Termination," published March, 2015, accessed February 29, 2016, 3. https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf

[8] Human Tissue Authority, "Guidance," 3–4.

[9] U.S. Department of Health and Human Services, *Informed Consent Tips (1993)*, prepared by the Office for Protection from Research Risks, last modified May 16, 1993, accessed February 29, 2016, http://www.hhs.gov/ohrp/policy/ictips.html.

[10] Exhibit A-3.

[11] Laura A. Siminoff and Heather M. Traino, "Consenting to Donation: An Examination of Current Practice in Informed Consent for Tissue Donation in the US." *Cell Tissue Bank* 14, no. 1 (2013): 85–95

[12] Exhibit A-2.

[13] 42 U.S.C. §289g-(b)(2)(A)(ii).

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

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Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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March 23, 2016

Ms. R. Alta Charo
Warren P. Knowles Professor of Law and Bioethics
University of Wisconsin
975 Bascom Mall
Madison, WI 53706

Dear Ms. Charo:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, March 2, 2016, to testify at the hearing entitled "Bioethics and Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: The Honorable Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

UNIVERSITY of WISCONSIN LAW SCHOOL

March 30, 2016

I am writing in response to the letter of March 23 from Marsha Blackburn, Chairman of the Select Investigative Panel of the House Committee on Energy and Commerce. In that letter, Chairman Blackburn posed three questions regarding my testimony at the March 2, 2016 hearing on "Bioethics and Fetal Tissue." Below you will find the three questions and my responses.

Question: In response to a question (referencing exhibits A-3 and C1-2) about whether a woman considering donating fetal tissue should know "specifically what it's going for and what the specific tissues to be used are going to be?" you replied "I'm not sure". Is it not true that providing such information would allow a woman to make a more informed choice before choosing to donate fetal tissue?

Also, identify any ethical concerns you have in regards to exhibit A-3, with particular focus on the following statement: "Research using the blood from pregnant women and tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's, Alzheimer's disease, cancer, and AIDS". Do you agree with Dr. Goldstein that this is a deceptive representation?

Response:

Consent is a process and a conversation. The forms are documentation of that process, but not the consent itself, and are not necessarily a complete representation of the information given or the conversations had in the process of obtaining consent. I cannot confirm or deny your interpretation of Dr. Goldstein's views, but for my own part, I find the forms to be accurate though perhaps not ideally written. These tissues have indeed been used to try to treat and cure diseases, as described, but there could be more emphasis on the fact that these diseases have not been conquered. Of course, most people are fully aware that these diseases have not yet been cured.

Overall, I know of no evidence that any woman chose to donate when further information of this sort would have altered her decision. As to the specificity of tissues and uses, it is worth noting that the Reagan panel recommendations and the federal rules both forbid "directed donation," precisely to avoid unduly influencing a woman in her decision to donate tissue. As a general matter, tissue may be collected in a wide variety of circumstances from living adults and from cadavers, with consent for its use in broadly defined areas of research.

Question: When asked whether any business or clinic should sell fetal tissue for a profit, you stated, "It is against the law." Do you think it is unethical for a business or clinic to sell fetal tissue for a profit?

Response: It is unethical to violate the law, which states that fetal tissue may not be sold for a profit.

University of Wisconsin Law School
University of Wisconsin-Madison 975 Bascom Madison, Wisconsin 53706

UNIVERSITY of WISCONSIN LAW SCHOOL

Question: In response to a question about cosmetics and the use of fetal tissue, you testified, "I find the cosmetic uses (not skin grafts) in Hollywood sometimes to be so frivolous that I'd be perfectly happy to see us abandon them." Please elaborate as to which uses of fetal tissue for cosmetic purposes (lotions, aging cream, etc.) you believe to be frivolous. Is fetal tissue used for other purposes that you believe does not represent a compelling public interest? If so, please identify these uses.

Response: I am unaware of any cosmetic uses of fetal tissue. In my responses to both of the questions concerning cosmetic uses, I spoke specifically about the full range of human tissues that are collected, which includes tissues collected from adult cadavers. Personally, I find some cosmetic uses of tissue from adult cadavers, for such things as lip plumping for persons who do not have an injury or other disfiguration, to be frivolous. I do understand, though, that these applications are legal.

Thank you for the opportunity to expand upon my testimony.

Very truly yours,

R. Alta Charo
Warren P. Knowles Professor of Law and Bioethics

University of Wisconsin Law School
University of Wisconsin-Madison 975 Bascom Madison, Wisconsin 53706

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
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COMMITTEE ON ENERGY AND COMMERCE

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March 23, 2016

Dr. Patrick Lee
Professor of Philosophy
Director, Center for Bioethics
Franciscan University of Steubenville
1235 University Boulevard
Steubenville, OH 43952

Dear Dr. Lee:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, March 2, 2016, to testify at the hearing entitled "Bioethics and Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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cc: The Honorable Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

Honorable Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

April 3, 2016

To Honorable Blackburn:

In response to the question relayed to me from March 23, 2016: I believe that was a remark from Representative Jerrold Nadler. Unfortunately, the Congressman's accusation was merely an *ad hominem* fallacy: instead of trying to show where he thought the argument advanced might be mistaken, the Congressman fallaciously attempted to discredit the person making the argument, and so the accusation was beside the point, that is, irrelevant to the question at issue.

In my testimony I pointed out that the evidence shows that what is killed in abortion is a **distinct** being—for the human embryo or fetus grows in his or her own distinct direction rather than as subordinated to the functioning of the maternal organism. The embryo or fetus is also obviously **human**—for his or her cells have the genetic structure characteristic of humans. And the human embryo or fetus is a **whole** human organism—as opposed to a part of a larger organism, as for example human tissue or a human organ—for he or she has all of the internal resources needed to actively develop himself or herself to the mature stage of a human being. All he or she needs is the appropriate environment, nutrition, and absence of disease or violence, to develop to full maturity. These points indicate just some of the clear evidence that shows beyond any reasonable doubt that the human embryo or fetus is a distinct, whole—albeit immature—human being, the same fundamental kind of being as you or me.

The basis for having fundamental rights is the fundamental kind of being one is, as opposed to any inessential attributes such as color, gender, size, or degree of development. Therefore it is unjust to provide protection of the law to born human beings but deny it to unborn human beings.

To subsidize and encourage the killing of unborn human beings—which is plainly what occurs with the funding of abortion providers—is an additional injustice.

Finally, since what is killed in abortion is a distinct human being, these victims of abortion are not, and should not be treated as, mere parts of their mothers. A mother who has chosen to abort a child indicates she no longer acts with the interests of the child as foremost. So, women have procured abortions lack the authority needed to be the appropriate decision-maker in regard to the use of that child's body after death. The point is not that she has become morally debased by that decision—as Congressman Nadler misinterpreted my argument during testimony—for, as I noted in my testimony, what she did may have been "done in confusion and with mitigated responsibility." Rather, the point is that by her decision to have the abortion she no longer stands in relation to the child as a parent acting primarily for that child's interests.

Patrick Lee

John N. and Jamie D. McAleer Professor of Bioethics

Franciscan University of Steubenville

FRED UPTON, MICHIGAN
CHAIRMAN

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ONE HUNDRED FOURTEENTH CONGRESS

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March 23, 2016

Dr. Kathleen Schmainda
Professor, Radiology and Biophysics
Vice-chair, Research
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226

Dear Dr. Schmainda:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, March 2, 2016, to testify at the hearing entitled "Bioethics and Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, April 6, 2016. Your responses should be mailed to Rachel Collins, Investigative Counsel and Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Rachel.Collins@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: The Honorable Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

United States House of Representatives
Select Panel of the Committee on Energy and Commerce
"Bioethics and Fetal Tissue"
Wednesday March 2, 2016

Response to Additional Questions for the Record
Submitted by: Kathleen M. Schmainda, PhD
April 8, 2016

The Honorable Marsha Blackburn

1. At the hearing, the claim was made that without fetal tissue, Zika virus research could not go forward. Only days later, the Washington Post cited a Cell Stem Cell research project in which induced pluripotent stem cells were engineered to study the characteristics of the virus's infectious potential in developing neural tissue. Since the breakthrough study produced vital information, why the insistence that fetal tissue is required to develop a vaccine or to study the infection's progress?

The answer following, does not get at the ***motivation*** for the insistence on fetal tissue, but gives you more background on the licit alternatives. The insistence seems to be motivated from a desire to continue the same research and cell sources (i.e., tradition, what's worked in the past), resistance to change (it might delay experiments), and likely an ideological undertone (failure to recognize the basis of the controversy, or to give any credence or consideration to alternative ethical viewpoint. This last point also seems to underlie the large-scale lack of acknowledgement for the successful research and proven cures using ethical alternatives.)

While the earliest attempts at growing viruses did use cultures of unpurified human fetal tissue, most research, as well as vaccine production, quickly shifted to purified cell lines which lent themselves to considerably less variability and provided large numbers of quality-controlled cells, providing reproducible results. In the 1960's and 1970's, cell culture work operated under an assumption that younger cells grew better, faster, and longer, so fetal cells obtained from abortion were sometimes used to create these cell lines (indicating they were developed as a lineage from a specific, original source of cells grown in the lab.) A few human fetal cell lines (WI-38, MRC-5) are still in use for some vaccine production. However, few vaccines are now produced using fetal cell lines, and none using fetal tissue. Newer cell lines, e.g., A549 cells (adult human),[1] Sf9 cells (insect),[2] EB66 (duck),[3] and better culture techniques make reliance on fetal cells an antiquated science. In addition, the CDC and other leading medical authorities have noted since 2001 that "No new fetal tissue is needed to produce cell lines to make these vaccines, now or in the future."[4]

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[1] See e.g., Shabram P and Kolman JL, Evaluation of A549 as a New Vaccine Cell Substrate: Digging Deeper with Massively Parallel Sequencing, *PDA J Pharm Sci Technol* 68, 639, 2014

[2] See e.g., Glenn GM et al., Safety and immunogenicity of a Sf9 insect cell-derived respiratory syncytial virus fusion protein nanoparticle vaccine, *Vaccine* 31, 524, 2013; AND Khan AS, FDA Memo: Cell Substrate Review for STN 125285, January 14, 2013; accessed at: http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM339125.pdf

[3] See e.g., Brown SW, Mehtali M, The Avian EB66(R) Cell Line, Application to Vaccines, and Therapeutic Protein Production, *PDA J Pharm Sci Technol.* 64, 419, 2010

[4] See, *e.g.*, "Vaccine Ingredients – Fetal Tissues," The Children's Hospital of Philadelphia, 2014; accessed July 21, 2015 at www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients/fetal-tissues; CDC quote originally accessed July 2015 at: http://www.ascb.org/newsfiles/fetaltissue.pdf

To summarize, early fetal tissue and cell lines used for vaccine development were developed using suboptimal methods. Consequently, these cell lines should not be considered a "gold standard" mode of vaccine development. Rather their continued use would be considered to be "bad science". Currently, there are plenty of ethical alternatives available for cell line development, all using better methodology.

The example referenced in the question is another clear answer for the lack of need for freshly aborted fetal tissue in virus and vaccine studies. Scientists developed a successful model system to show that the Zika virus can infect and damage some developing brain cells.[5] The established experimental model, which the authors of the paper note can now be used for further investigations of developing brain as well as screening therapeutic compounds, was not developed using fetal tissue. The successful system uses human induced pluripotent stem cells (iPS cells), which are ethically created from skin or other normal cell types; the development of iPS cells earned the 2012 Nobel Prize for Dr. Shinya Yamanaka of Japan.

Another recent study by a Brazilian group confirmed the susceptibility of developing human brain cells to Zika virus infection, with potential damage to infected brain cells. Again, the successful study did not use human fetal tissue, but rather human iPS cells.[6]

Human iPS cells have demonstrated excellent potential to model developing brain, producing what are termed "organoids" for detailed study of the various cell types, brain structures, and even abnormal development that can occur. In particular, one model system using human iPS cells to produce brain organoids has been shown also to be an accurate model to study Microcephaly, the brain development condition that seems to be associated with infection by Zika virus in the womb.[7] And a newly-published paper further validates the superior ability of human iPS cells to model brain development. While this new reference does discuss Zika in particular, it convincingly demonstrates that this model system for brain development – which does not use aborted human fetal tissue – can be used to model normal human brain development, the timing of brain development associated with production of various neuronal cell types, and even to compare human brain development versus that of monkeys.[8] (Note that the development of tissue organoids has become a primary focus of the newly established National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), thus lending further support for this avenue of research.)

Finally, development of a vaccine against Zika also would not need any aborted human fetal tissue. Modern vaccine development does not rely on fetal tissue or human fetal cell lines. Another recent example of this is the announced success of a field test of a vaccine against Dengue virus, a close relative of Zika.[9] The vaccine provided 100% protection,[10] but was developed using monkey cells and a mosquito cell line.[11]

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[5] Tang H *et al.*, Zika Virus Infects Human Cortical Neural Progenitors and Attenuates Their Growth, *Cell Stem Cell* 18, 2016; *in press*, doi: 10.1016/j.stem.2016.02.016

[6] Garcez PP *et al.*, Zika virus impairs growth in human neurospheres and brain organoids, *PeerJ Preprints* 4:e1817v3; doi: 10.7287/peerj.preprints.1817v3

[7] Lancaster MA *et al.*, Cerebral organoids model human brain development and microcephaly, *Nature* 501, 373, 19 Sept 2013

[8] Otani T *et al.*, 2D and 3D Stem Cell Models of Primate Cortical Development Identify Species-Specific Differences in Progenitor Behavior Contributing to Brain Size, *Cell Stem Cell* published online March 31, 2016, doi: 10.1016/j.stem.2016.03.003.

[9] Kirkpatrick BD *et al.*, The live attenuated dengue vaccine TV003 elicits complete protection against dengue in a human challenge model, *Sci. Transl. Med.* 8, 330ra36, 2016.

[10] Check Hayden E, Dengue vaccine aces trailblazing trial, *Nature*, 16 March 2016, doi: 10.1038/nature.2016.19576

[11] Men R et al., Dengue Type 4 Virus Mutants Containing Deletions in the 39 Noncoding Region of the RNA Genome: Analysis of Growth Restriction in Cell Culture and Altered Viremia Pattern and Immunogenicity in Rhesus Monkeys, *J.*

2. At the hearing, you made an important statement regarding the Polio vaccine. Can you explain for the Panel, what tissues were actually used for the Polio vaccine?

The earliest attempts at growing viruses sometimes used cultures of mixed fetal tissue, but not individual cultured cells. For example, the proof of principle experiment showing that polio virus could be grown in non-nervous tissue culture in 1949, used human fetal tissue.[12] But it is not true that the 1954 Nobel prize given to Enders et al. was for production of polio vaccine, nor even for growth of enough virus used to produce the polio vaccine. The fact is, the original Salk and Sabin vaccines were both produced using laboratory-cultured monkey tissue.[13] Later, poliovirus was produced in human fetal cell lines (WI-38, 1961,[14] fetal female lung; MRC-5, 1966, [15]fetal male lung), but also in HeLa cells,[16] a human cancer cell line that is not made from fetal tissue. Most modern manufacturers of polio vaccine now use other specific cell types including monkey cells; most do not use any human fetal cells, and none use freshly aborted fetal tissue. No current vaccines are made using fresh aborted fetal tissue.

In the 1960's and 1970's, cell culture work operated under an assumption that younger cells were better, grew faster, lived longer, so fetal cells obtained from abortion were sometimes used. These cells[17]adapted to lab culture and continued to grow, becoming known as a "cell line" because they developed as a lineage from different, specific cells grown in the lab. While a few human fetal cell lines (WI-38, MRC-5) are still in use for some vaccine production,[18] few vaccines are now produced using fetal cell lines, and **none using fetal tissue**.

Finally, there remain significant, unresolved questions on the public health dangers of produets resulting from use of aborted fetal cell lines; these potential health concerns should also be investigated, as well as identification of non-controversial replacements for such fetal cell lines.

Virology 70, 3930, 1996; and Medina F et al., Dengue Virus: Isolation, Propagation, Quantification, and Storage, *Current Protocols in Microbiology* 15D.2.1-15D.2.24, November 2012

[12] Enders JF *et al.*, Cultivation of the Lansing strain of poliomyelitis virus in cultures of various human embryonic tissues, *Science* 109, 85, 1949

[13] Salk JE, Recent Studies on Immunization against Poliomyelitis, *Pediatrics* 12, 471, 1953; and Salk JE *et al.*, Formaldehyde Treatment and Safety Testing of Experimental Poliomyelitis Vaccines, *Am. J. Public Health* 44, 563, 1954; and Salk JE *et al.*, Studies in Human Subjects on Active Immunization Against Poliomyelitis II. A Practical Means for Inducing and Maintaining Antibody Formation, *Am. J. Public Health* 44, 994, 1954; and Sabin AB, Present status of attenuated live-virus poliomyelitis vaccine, *JAMA* 162, 1589, 1956

[14] Original fetal cell cultivations 1961, original poliovirus growth 1962 in WI-1, standardized in WI-38; Hayflick L, Moorhead PS, The serial cultivation of human diploid cell strains, *Experimental Cell Research* 25, 585, 1961; Hayflick L *et al.*, Preparation of poliovirus vaccines in a human fetal diploid cell strain, *Am. J. Hyg.* 75, 240, 1962; Hayflick L, The limited in vitro lifetime of human diploid cell strains, *Exp. Cell Res.* 37, 614, 1965.

[15] Jacobs JP *et al.*, Characteristics of a Human Diploid Cell Designated MRC-5, *Nature* 227, 168, 1970

[16] Scherer WF *et al.*, Studies on the propagation in vitro of poliomyelitis viruses. IV. Viral multiplication in a stable strain of human malignant epithelial cells (strain HeLa) derived from an epidermoid carcinoma of the cervix, *J. Exp. Med.* 97, 695, 1953

[17]

[18] CDC, Appendix B: Vaccine Excipient & Media Summary, Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook - 13th Edition, 2015; accessed at: http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

3. At the hearing, you made a statement about how many fetuses it would take to provide a therapeutic intervention for the European Parkinson's experiments. Can you provide the source for this information? Also, can you elaborate on the ethical implications for any therapy that depends on a significant volume of fetal tissue?

Clinical trials were performed in Sweden, for which cells from at least 3-4 fetuses were needed to treat each Parkinson's patient. This study was the topic of a New York Times article[19], and described by those who performed the study in a scientific paper published in that same year[20]. While the authors claimed procedural success, no significant benefit to the patients was reported.

Overall, between 1988 and 1994, roughly 140 Parkinson's disease patients received fetal tissue (**up to six fetuses per patient**), with varying results.[21] Subsequent reports showed that severe problems developed from fetal tissue transplants. One patient who received transplant of fetal brain tissue (from a total of 3 fetuses) died subsequently, and at autopsy was found to have various non-brain tissues (*e.g.* skin-like tissue, hair, cartilage, and other tissue nodules) growing in his brain.[22]

In 2001, the first report of a full clinical trial[23] (funded by NIH) using fetal tissue for Parkinson's patients was prominently featured in the *New York Times*,[24] with doctors' descriptions of patients writhing, twisting, and jerking with uncontrollable movements; the doctors called the results "absolutely devastating", "tragic, catastrophic", and labeled the results "a real nightmare."

A second large, controlled study published in 2003 showed similar results (funded by NIH), with over half of the patients developing potentially disabling tremors caused by the fetal brain tissue transplants.[25] The results of these two large studies led to a moratorium on fetal tissue transplants for Parkinson's. Long-term follow-up of a few of the patients in these large studies showed that even in fetal tissue that grew in patients' brains, the grafted tissue took on signs of the disease and were not effective.[26]

A primary point of providing this information is that despite the many failed experiments, and loss of many lives in the process, many continue to contend that such studies should continue because there is still hope that one day they will prove successful. It is therefore necessary to consider a future where this proved true. Given that tissue transplants from 3-4 fetuses were needed to treat each Parkinson's patient, 4 million babies would need to be aborted to treat the 1 million patients currently living with this disease, in the US alone. Imagine the magnitude of the demand for fetuses to cure yet another disease such as Alzheimer's, which affects 44 million persons worldwide? Continuing down this path of pursuing treatments that require abortion-derived fetal tissue would create the industrialized harvesting of preborn babies.

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[19] Kolata, F., Fetal Tissue Seems to Aid Parkinson Patient, in The New York Times. February 2, 1990.
[20] Lindvall O et al., Neural transplantation in Parkinson's disease: the Swedish experience. Prog Brain Res. 82, 729-34 (1990).
[21] Reviewed in: Fine A, Transplantation of fetal cells and tissue: an overview, *Can Med Assoc J* 151, 1261, 1994
[22] Folkerth RD, Durso R, Survival and proliferation of nonneural tissues, with obstruction of cerebral ventricles, in a parkinsonian patient treated with fetal allografts, *Neurology* 46, 1219, 1996
[23] Freed CR *et al.*, Transplantation of embryonic dopamine neurons for severe parkinson's disease, *N Engl J Med* 344, 710, 2001
[24] Gina Kolata, "Parkinson's Research Is Set Back by Failure of Fetal Cell Implants," *New York Times* March 8, 2001; accessed at: http://www.nytimes.com/2001/03/08/health/08PARK.html
[25] Olanow CW *et al.*, A Double-blind Controlled Trial of Bilateral Fetal Nigral Transplantation in Parkinson's Disease, *Ann Neurol* 54, 403, 2003
[26] Braak H, Del Tredici K, Assessing fetal nerve cell grafts in Parkinson's disease, *Nature Medicine* 14, 483, 2008

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

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Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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March 23, 2016

Dr. Lawrence Goldstein
Sanford Consortium for Regenerative Medicine
2880 Torrey Pines Scenic Drive
La Jolla, CA 92037

Dear Dr. Goldstein:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, March 2, 2016, to testify at the hearing entitled "Bioethics and Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: The Honorable Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

The Honorable Marsha Blackburn

1. At the hearing, the claim was made that without fetal tissue, Zika virus research could not go forward. Only days later, the Washington Post1 cited a Cell Stem Cell research project in which induced pluripotent stem cells were engineered to study the characteristics of the virus's infectious potential in developing neural tissue. Since the breakthrough study produced vital information, why the insistence that fetal tissue is required to develop a vaccine or to study the infection's progress?

Answer: Respectfully, my own testimony did *not* state that "Zika virus research could not go forward. " I did, however, argue that it would be slowed without fetal tissue research. The Cell Stem Cell study cited in the Washington Post (Tang et al., Cell Stem Cell 2016) was indeed interesting in this context as it demonstrated enhanced infection of neural progenitors made from pluripotent stem cells. Thus, this paper perhaps provides an important clue to a cell type that Zika might infect. Interestingly, the Tang et al. paper uses HEK293, which are cells of fetal origin further underscoring the important need for fetal tissue in research. But, importantly, the Tang et al. Cell Stem Cell paper relies on the hypothesis that Zika directly infects the fetal brain as opposed to generating placental defects or other defects in the mother during pregnancy. This important evidence comes in part from a previous paper by *Mlakar et al., NEJM 2016 mar 10 vol 374 p951* that depended heavily upon fetal tissue for the conclusion that Zika virus infects the fetal brain directly. The genome structure of the Zika virus was also worked out in Mlakar et al, which is critical for future work. Without this analysis of donated abortion-derived fetal tissue provided in Mlakar et al., we would lack important evidence that the Zika virus actually infects the fetal brain, which was the foundation for the Cell Stem Cell paper.

Furthermore, the Tang et al. Cell Stem Cell paper is highly limited and only shows that one type of cell, a neural progenitor cell can be made with pluripotent stem cells and infected by Zika. But the Tang et al. paper provides no evidence that this progenitor is the actual cell type infected in the fetal brain. The fetal and adult brain are composed of many cell types including astrocytes, oligodendrocytes, and different types of progenitors in different regions. Neural progenitors themselves can be highly variable with regional identities that may or may not correspond to bona fide fetal brain cell types. The Tang et al. Cell Stem Cell paper does not examine any of these other cell types and so is highly limited. Most important, any cell type predicted by in vitro cell culture work to be the primary target of Zika will almost surely need to be verified in bona fide fetal brain tissue during the course of an infection before subjecting at-risk mothers to preventative or disease modifying therapies.

A more recent paper was just published in Cell Stem Cell by Nowakowski et al. (2016) that made extensive use of fetal brain tissue to determine in greater detail the cell type infected by Zika virus in the fetal brain and went further to determine the potential molecules that the virus uses to attack fetal brain cells. The paper by Nowakowski et al. goes well beyond the Tang et al. paper reported in the Washington Post and highlights how important fetal tissue is to identify the correct brain cells infected by the virus and the mechanism used so that potential therapies or vaccines may be developed.

2. First of all, you mention fetal cells related to spinal cord injuries – Why don't you tell us about any peer reviewed journal studies about the cures of spinal cord injuries from adult stems cells?

Answer: I am not sure which studies you are referring to, but I'll note that I am aware of a few sporadic studies of different cell types for spinal cord injury that claim results of varying quality. First, I told you about fetal tissue since that was the subject of the hearing. Second, some of the spinal cord injury studies claiming "cures" from injections of adult cells are poorly controlled and designed so that it is not possible to determine whether any beneficial effects were from the cells or from the accompanying intensive physical therapy or from occasional sporadic improvements. Third, patients in some of these reports suffered adverse events including benign tumors, payment of large amount of money without benefit, and worsening of function. One patient in particular treated with adult olfactory cells developed a spinal tumor at the site of transplant (Diouhy et al. J. Neurosurg Spine 2014). The point is that many types of cells need to be tested, including adult cells, embryonic cells, and fetal neural stem cells to find out what is the best therapy. It makes no sense to only try one approach and so the scientific community is pursuing many avenues in parallel to find relief for the many spinal cord injury victims that need help. Many such trials using different types of cells including fetal cells are listed in clinicaltrials.gov.

You told us that fetal cells are essential to make astrocytes but you did not mention that adult neural stem cells can make astrocytes and perform what the fetal cells are doing. Aren't the fetal cells in your testimony just "nurse" cells to spew growth factors out to support iPS cells.

Answer: Astrocytes are beginning to be recognized as cells that provide more than just growth factors. We use astrocytes in our experiments in a number of ways, sometimes just for the factors they produce. Not all astrocytes produced in vitro are identical to each other or to natural sources. We also don't yet know the nature of all of the factors produced by astrocytes. Continued work comparing fetal astrocytes to other sources of astrocytes will be useful. Moreover, astrocytes derived from fetal material grow more successfully in the lab environment than do adult-derived astrocytes.

Why did your testimony fail to mention that functional kidney "organoids" have already been grown using iPS cells and adult stem cells.

Answer: Thank you for raising the kidney organoid experiments, which are instructive. In the Nature paper reporting kidney organoids, stem cells were used to make structures that had some of the functional elements of kidneys although they were disorganized. Notably, the paper reporting on kidney organoids makes extensive use of *fetal tissue* as a comparison to evaluate how similar organoids were to *fetal kidneys*. This paper is a particularly good example of how important fetal tissue research is to ongoing research to develop organs from stem cells.

3. Prior to providing consent to donate fetal tissue, should a woman be advised that there is a possibility her child may be "born alive"?

Answer: This question is outside my field of expertise.

Is it not true that such information would allow a woman to provide a more informed consent prior to deciding whether to donate tissue, thereby making the consent more ethically sound?

Answer: This question is outside my field of expertise.

If you respond in the negative, please identify specific reasons why such information is ethically irrelevant.

4. In response to a question about "where do you guys get your fetal tissue," you testified that the "fetal neural stem cells that we obtain for our clinical trials come from our collaborating company called Neuralstem." You further testified that you "honestly don't know where they (Neuralstem) obtain their tissue." Since you are involved in transplantation research, do you know which DHHS regulations Title 45 Part 46 Regulations for an IRB were complied with? If so please provide these IRB approvals for the Panel.

Answer: The current work of the Sanford Stem Cell Clinical Center, which I direct collaborates with Neuralstem using an established cell line named NSI-566 and does not include procurement of new tissue. My understanding is that use of these cells is exempt from DHHS regulation Title 45 Part 46. DHHS regulations under Title 45 Part 46 apply only to federally funded human research. Nonetheless, our work with human subjects suffering from spinal injury is subject to federal regulatory oversight under Title 21 Part 50 and was approved by an IRB having satisfied all elements outlined in Title 21 Part 50. Moreover, this research is closely monitored by an IRB as required by Title 21 Part 50 . I have been advised that the IRB documents may be UCSD property and so should be requested from UCSD.

Do you currently obtain fetal tissue from sources other than Neuralstem? Have you obtained fetal tissue from other entities in the past?

Answer: My lab obtains fetal astrocytes from Lonza and immortalized fetal astrocytes from ABM. We also use the established cell line HEK 293, I have not personally obtained fetal tissue from other entities in the past.

---

1 See https://www.washingtonpost.com/national/health-science/evidence-of-zikas-risk-to-pregnant-womencontinues-to-grow/2016/03/05/6c8e6152-e2aa-11e5-8c00-8aa03741dced_story.html.

The Honorable Joseph R. Pitts

Mr. Goldstein, you testified that the "form that says therapies for diseases such as Alzheimer's disease and all the rest have already been found, I agree, that is an inappropriate statement and it should not have been made on that form. I don't know who wrote it. That would not have made it past my IRB either." You were also asked where you get fetal tissue for your research. You responded that the fetal tissue neural cells come from Neuralstem and you don't know where they get the fetal remains from which to start the cell lines.

Following up on those statements:

1. How many research projects involving organs, tissue or cells from aborted babies have you participated in? Which of these were conducted in collaboration with Neuralstem?

Answer: My lab uses fetal astrocytes for our varied studies of Alzheimers Disease, therefore, approximately 6 projects use these cells. I also serve as director of a center (Sanford Stem Cell Clinical Center) that uses established fetal neural stem cell lines from a company called Neuralstem in clinical trials for spinal cord injury. I also chair an oversight committee that used fetal tissue in the past to develop a therapy for multiple sclerosis. Finally, I chair an executive committee of a multi-investigator project aimed at developing kidneys from stem cells. Several of the projects in this kidney collaboration use fetal material including the kidney organoid study that you cited during the hearing.

2. Did you obtain IRB approval for all of the projects involving human fetal tissue, organs, cells or cell lines that you have conducted or in which you have participated? What standards did your IRB set for ethically obtaining human fetal tissue in each?

Answer: We obtain IRB approvals as required in full accordance with federal regulations. My understanding of the rules is that if the research with established cell lines from fetal material does not involve interaction with living or identifiable human subjects (that is, laboratory work), that research is exempt from IRB approval. All of our work involving human tissue donors or patients participating in clinical trials is compliant with regulations under Title 45 Part 46 and is reviewed and approved by an appropriately convened IRB.

3. Please indicate the source of the fetal organs or cells for each project, the informed consent forms used in each (any patient-identifying information should be redacted), and the amount paid for each.

Answer: In our Alzheimer Disease studies, established fetal astrocyte lines and immortalized fetal astrocyte lines are grown and expanded substantially by a company, Lonza, using fetal brain as a starting material; these are effectively an established cell line and therefore exempt from DHHS or FDA regulations for protection of human subjects. Lonza normal human astrocytes are listed for $695 for one million cells. ABM immortalized astrocytes are listed for $1350 for one million cells.

My understanding is that informed consent documents are the property of the companies who grow the cells and are generally maintained by these companies to document the ethical procurement of the research material. For our work in 2012 published in Nature,

we obtained data from a colleague who had previously studied gene expression patterns in fetal brain. Since I was not the attending physician (I am not a physician), I do not have the relevant documents and have been advised that such documents may be UCSD property and so should be requested from UCSD.

In the collaborative spinal cord injury trials, fetal neural stem cells are obtained without cost in this collaborative trial. In the projects in which I participate in an oversight role, I do not have direct access to materials or documents.

4. With regard to your collaboration with Neuralstem or any similar intermediary, please obtain the information requested in question 3 from Neuralstem (or any other intermediary).

Answer: I do not have access to any of these documents. They belong to Neuralstem, to Lonza, and to ABM.

5. You indicated a form presented at the hearing that overstated cures would not make it past your IRB. That same statement appears on forms that Planned Parenthood uses (according to this). You co-authored this study regarding Alzheimer's. In the study, published in 2012, you thank "Planned Parenthood of the Pacific Southwest for fetal brain specimens." Redacting any patient identifying information, please provide a copy of the informed consent forms used for each specimen (fetal organ, tissue, cells or cell lines).

Answer: For our work in 2012 published in Nature, we obtained data from a colleague, another PI, who had previously studied gene expression patterns in fetal brain. Since I was not the attending physician (I am not a physician), and did not interact with the donors of material, I do not have the relevant documents and have been advised that such documents are UCSD property and so should be requested from UCSD. I would also like to point out that sharing of personal information (such as a signature or name on a research informed consent document) with individuals who are not otherwise authorized to access these documents (such as the FDA or the IRB), violates the confidentiality research participants expect (and is often made explicit in the consent form). For this reason, I would normally not be permitted to have access to consent forms signed by individuals from collaborating institutions or individuals (whether they are private companies or universities).

The Honorable Janice D. Schakowsky

During the March 2, 2016 Select Investigative Panel hearing, questions were raised concerning the significance of recent fetal tissue donation to advancing our understanding of human development, disease, and illness and to conducting research on potentially lifesaving treatments and cures.

As a distinguished practicing scientist for 40 years, you have a wealth of experience working with a range of cells and tissue as part of your efforts to understand and treat Alzheimer's disease, spinal cord injury, ALS (sometimes called Lou Gehrig's disease), and kidney disease. You are also likely familiar with the work of other researchers who use fetal tissue to understand and seek treatment for a range of other illnesses or diseases.

1. While some of your research may use established cell lines, is there still a need for ongoing fetal tissue donation? (If your answer is yes, please provide some representative examples that illustrate the ongoing need for fetal tissue donation.)

Answer: yes. There still is a need for new fetal tissue for studies of kidney development and development of other organs. While part of the work can be done with established cell lines, newer methods may generate better quality cell lines for therapeutic clinical trials. In addition, as investigators try to develop organs from stem cells in the lab, there will be continued need to compare the behavior of these organs to bona fide fetal tissue, especially for gene expression patterns in highly specialized cell types. Fetal tissue is the gold standard for these investigations and tissues otherwise destined for discard will be very valuable to the validity, quality, and reliability of studies trying to make organs in the lab from stem cells. It is likely that work that is developing organs from stem cells will continue to need comparative data from fetal and adult sources going forward. New ideas developed in the future about spinal cord injury treatment and other treatments, e.g., recent work about neonatal and fetal eye development, will likely continue to need new fetal tissue for comparative purposes or as actual sources.

I also want to point out that there are a number of clinical trials that are using cells derived from fetal tissue to treat patients for a variety of indications. For example:

- human fetal liver transplantation for the treatment of liver cirrhosis (Clinicaltrials.gov #NCT01013194)
- human fetal neuron transplantation for the treatment of huntington's disease (Clinicaltrials.gov #NCT00190450)
- human fetal neural progenitors for the treatment of parkinson's disease (Clinicaltrials.gov #NCT01860794)

Obviously, there are many physicians and scientists whose expert opinion is that treatment with fetal cells offers therapeutic options in certain contexts that do not exist otherwise.

2. Can anyone predict the types of cells or systems that will be necessary for answering particular research questions or developing new treatments or cures going forward?

Answer: Nobody can reliably predict the future. That is why we must as scientists pursue multiple paths in parallel to fight disease. Adult stem cells, fetal tissues, and embryonic stem cells all are potent weapons in the fight against disease and play a role

in investigations that should be pursued in parallel to find useful therapies as rapidly as possible for people suffering from disease. Some stem cells and tissues will be better for research and therapy than others. It is not one size fits all; we need a variety of cell types to fight disease just as we need more than one antibiotic to fight different types of infections. In addition, time matters to people suffering from fatal or disabling disease. Thus, we must proceed as rapidly, ethically, and efficiently as possible to help these people in need of medical and scientific help.

THE PRICING OF FETAL TISSUE

WEDNESDAY, APRIL 20, 2016

HOUSE OF REPRESENTATIVES,
SELECT INVESTIGATIVE PANEL,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The panel met, pursuant to call, at 10:00 a.m., in Room HVC–210, House Visitors Center, Hon. Marsha Blackburn (chairman of the panel) presiding.

Members present: Representatives Blackburn, Pitts, Black, Bucshon, Duffy, Harris, Hartzler, Love, Schakowsky, Nadler, DeGette, Speier, DelBene, and Watson Coleman.

Staff present: March Bell, Staff Director; Mike Bloomquist, Deputy Staff Director; Karen Christian, General Counsel; Rachel Collins, Investigative Counsel and Clerk; Chuck Flint, Legislative Director (Rep. Blackburn); Jay Gulshen, Staff Assistant; Mary Harned, Investigative Counsel; Pierre Kamga, Detailee, GAO; Peter Kielty, Deputy General Counsel; Graham Pittman, Legislative Clerk; Mike Reynard, Communications Director; Frank Scaturro, Special Counsel; Heidi Stirrup, Health Policy Coordinator; Matthew Tallmer, Investigator; Jean Woodrow, Director, Information Technology; Zachary Baron, Democratic Senior Investigative Counsel; Paul Bell, Democratic Communications Advisor; Jacquelyn Bolen, Democratic Investigative Counsel; Vanessa Cramer, Democratic Professional Staff Member; Matthew Henry, Democratic Fellow; Chava Kahn, Democratic Fellow; Karen Lightfoot, Democratic Communications Director/Senior Policy Advisor; and Heather Sawyer, Democratic Staff Director.

Mrs. BLACKBURN. The Select Investigative Panel will come to order. And before we begin, I would like to take a moment to address the guests who are in our audience today.

First of all, we thank each of you for taking the time to come. We think that engaged citizens are a welcome and valuable part of the political process. I only wish every hearing drew the amount of interest that this hearing has drawn.

For the purpose of this hearing, we are going to be examining the pricing of fetal tissue. It is an opportunity for the Select Investigative Panel to ask questions and have a thoughtful discussion. The number of people in the audience this morning demonstrates the strong interest in the topic, and we welcome you.

I do want to remind our guests in the audience that the Chair is obligated under the rules of the House and the rules of the committee to maintain order and preserve decorum in the committee room. And I know that we all have deep feelings on the issue, but we appreciate the audience's cooperation in maintaining order, as we have a full discussion that we would like to have this morning on this important issue.

I also want to welcome each of our witnesses who are here today. And at this time, I am going to yield myself 10 minutes for an opening statement.

Ms. DEGETTE. Madam Chair?

Mrs. BLACKBURN. The gentlelady is recognized.

Ms. DEGETTE. Thank you, Madam Chair. Regretfully, I need to bring up an issue regarding the packet of materials, the so-called exhibits, that was provided by your staff yesterday before the opening statements. And the reason is because we have just received your opening statement, which was released to the press.

I just saw it for the first time, and in your opening statement you make extensive reference to this package of so-called exhibits. And so before you make your opening statement, maybe we can resolve the issues. Otherwise, we are going to even have to object to the documents referenced in your opening statement.

And if I may, Madam Chair, I will go over what our issues are with those so-called exhibits. Your staff told us that you and other Republican Members intended to use these materials to question witnesses today, and it is my understanding that these documents have been given to the witnesses. In fact, several of the witnesses mentioned the documents in their written statements.

Now, I reviewed the documents yesterday. Some of them were created wholesale by Republican staff. There was no explanation of the underlying factual foundation for those materials, the methodology that was used in coming up with these charts, or some of the graphs that we had and, frankly, I believe them to be misleading. Moreover, the conclusions that are drawn and, frankly, stated as fact in the staff-created annotated index are false.

There were other documents that were sourced to a "procurement business" which also have nothing to do with the topic of this hearing, although they were presented as if they did. They don't distinguish between the various services of the company, which provides a variety of different specimens, including adult blood and bone marrow for use in biomedical research.

Now, just to add to this, Madam Chair, yesterday the company who we believe these so-called exhibits came from, StemExpress, sent a letter to you and a copy to us about the serious, serious problems with these so-called exhibits. I would ask unanimous consent to put that into the record.

But I guess my point is, I am concerned because the so-called exhibits, I don't think they are really designed to find the facts about fetal tissue research. If they were, we would have called StemExpress in, or we would have taken depositions. And I don't believe that they are germane as required by Rule 16, Clause 7 of the House, because they don't reflect credibility but, instead, they cast dishonor on the House.

But, you know, in addition, if I just may, because we just got these exhibits yesterday and then we got the letter from StemExpress, it also raises troubling questions about where this material came from. If you look at StemExpress' letter—and I hope you have read it, Madam Chair—what StemExpress is saying is they believe that the Panel may have received material directly from Mr. David Daleiden that has not been authenticated and that was obtained by Mr. Daleiden unlawfully.

This is part of the whole issue of the investigation in Texas, and some of these even may have been created by Mr. Daleiden himself. And what the company did was, they asked that we withdraw these documents until the general counsel of the House of Rep-

resentatives, Kerry W. Kircher, has an opportunity to review them and approve their list.

And so, Madam Chair, given the concerns about the factual foundations of these exhibits, and also given the further concern about how they were created, what they are saying, I would just ask if we could withdraw these exhibits until these things are figured out.

Mrs. BLACKBURN. I thank the gentlelady for her inquiry. Yes, we were in receipt of the letter. I don't know anything about the attorney or how truthful their letter is. We do intend and will accept—I accept your request, and we will UC that letter into the record for the hearing today.

[The information appears at the conclusion of the hearing.]

The documents, let me speak to that for a moment. The documents have all been obtained through our regular investigatory work. We have had things that have come to us from whistleblowers, from subpoenas, from former employees, citizens that have filed FOIA requests, the Panel's whistleblower portal, as I said, and also an Internet archive search engine. And that is the way these documents have come to us.

So the documents that we are going to use for the hearing, or the documents that we intend to use for the hearing, we will accept and UC the letter into the record. And when——

Ms. DEGETTE. But, Madam Chair, may I make a farther parliamentary——

Mrs. BLACKBURN. Parliamentary inquiry. Go ahead.

Ms. DEGETTE. Madam Chair, you had just stated that all of the documents that formed the basis of these exhibits were received from a variety of sources by the committee, including whistleblowers. Have all of those documents and their sources been provided to the minority staff of this committee?

Mrs. BLACKBURN. We have provided documents to the minority staff.

Ms. DEGETTE. Have you provided all of the documents, Madam Chair, that you refer to that were used as the foundation for these exhibits?

Mrs. BLACKBURN. I think all of those documents have been provided to you, and then you all leaked—you have staff that leaked the documents to one of the entities.

Ms. DEGETTE. OK. So they have all been—OK. Madam Chair, I would ask a further parliamentary inquiry then. Before we continue, then, might I be asked to inquire of the appropriate staff member of the foundational basis for these exhibits, particularly Exhibits B1, B2, some of those—there is a chart, Exhibit B4—which you intend to use.

There is an Exhibit B6, an excerpt of a draft contract between the PB and abortion trade association, which appears to have been created by staff. I would like to be able to ask the staff how these documents were created and what——

Mrs. BLACKBURN. What do you mean by "foundational basis"?

Ms. DEGETTE. Well, for example, Madam Chair, if you take a look at Exhibit B1. So Exhibit B1, Madam Chair, appears to be a chart, and it has three boxes—Abortion Clinic, Procurement Business, Researcher—and between the three boxes there are dollar

signs and arrows going back and forth, there are questions, and so on.

I don't know what information this is based on. I would like to know how this was created. Or, if you look at Exhibit B2, for example, Exhibit B2 is some document. It doesn't say where it is from. It appears to have been taken from some Web site, but this is one of the documents that StemExpress is saying that they think might have been taken from—not from their company, but from someplace else, and not talking about fetal tissue. But I don't know where that comes from.

The exhibit is not identified where it comes from, but I suspect that the witnesses today and the majority intend to somehow try to use this to talk about the so-called sale of fetal tissue.

Exhibit 3 is just, again, something taken off a Web site. We don't know the source of that. Exhibit 4 appears to be a bar graph, and what it says is, "Procurement Business' Clinic Growth Strategy: Number of partnerships with abortion clinics," then it has got a bar graph.

Then Exhibit B5, "Procurement Business' Revenue Growth," then it has got another bar graph, but we don't know who made those bar charts and we don't know where that information came from. So, if you or the witnesses are relying on this, this is being presented as if it is a fact, but in fact it is not.

And then B6, this is one that particularly disturbs me. It says in parentheses "Excerpt of a draft contract between the PB and the abortion"——

Mrs. BLACKBURN. If the gentlelady will yield?

Ms. DEGETTE. Sure.

Mrs. BLACKBURN. OK. The B1 graph that you are referencing was created by staff for discussion purposes. It is created by material that has been submitted to us, to the committee. And so the document B2 exhibit that you are going to is something, again, that was submitted to us, and B4 is something created by staff from material that has been submitted.

Now, does the gentlelady have a motion?

Ms. DEGETTE. Yes. Just to finish my statement, Madam Chair, that is my concern. I would like to be able to question the staff member who created all of these documents. I assume——

Mrs. BLACKBURN. They are created for discussion, and if you would like to include in your questioning, in your time, discussion about that, that is fine.

Ms. DEGETTE. Well, Madam Chair, I think that these exhibits were created from whole cloth. And if you won't let me find out what the bases for these are, then I object to the use of any——

Mrs. BLACKBURN. I would——

Ms. DEGETTE [continuing]. Of these exhibits——

Mrs. BLACKBURN. I would——

Ms. DEGETTE [continuing]. And I——

Mrs. BLACKBURN [continuing]. The gentlelady that information has been submitted to us.

Ms. DEGETTE. And I would make a point of order that these materials are against Rule 16, Clause 7 of the House, and I would ask for their exclusion.

Mr. DUFFY. Madam Chair, I move to table the point of order.

Mrs. BLACKBURN. The gentlelady's motion has been——
Ms. DEGETTE. Madam Chair, I appeal the ruling of the Chair.
Mrs. BLACKBURN. The gentlelady's motion has been made, and the motion is tabled.
Ms. DEGETTE. Madam Chair, I appeal the ruling of the Chair. That was the motion I just made, Madam Chair.
Mrs. BLACKBURN. You made the motion to exclude.
Ms. DEGETTE. No. And then he moved——
Mrs. BLACKBURN. The motion to——
Ms. DEGETTE [continuing]. To table it, and then I moved to appeal, and then you ruled—you moved to table it, and I moved to appeal it.
Mrs. BLACKBURN. We will rule on the motion to table first.
Ms. DEGETTE. Yes.
Mrs. BLACKBURN. OK. And the motion is tabled.
Ms. DEGETTE. I appeal the ruling of the Chair.
Mrs. BLACKBURN. And the appeal——
Ms. DEGETTE. And I ask for a recorded vote.
Mrs. BLACKBURN. And the appeal is denied. We will have the clerk call the roll for the recorded vote on the motion to appeal.
The CLERK. Mr. Pitts?
Mr. PITTS. Yes.
The CLERK. Mr. Pitts says aye.
Ms. Black?
Ms. BLACK. Yes.
The CLERK. Mr. Pitts says aye. Ms. Black says aye.
Mr. Bucshon?
Mr. BUCSHON. Yes.
The CLERK. Mr. Bucshon says aye.
Mr. Duffy?
Mr. DUFFY. Aye.
The CLERK. Mr. Duffy says aye.
Mr. Harris?
Mr. HARRIS. Aye.
The CLERK. Mr. Harris says aye.
Mrs. Hartzler?
Mrs. HARTZLER. Aye.
The CLERK. Mrs. Hartzler says aye.
Mrs. Love?
Mrs. LOVE. Aye.
The CLERK. Mrs. Love says aye.
Ms. Schakowsky?
Ms. SCHAKOWSKY. No.
The CLERK. Ms. Schakowsky says nay.
Mr. Nadler?
[No response.]
Ms. DeGette?
Ms. DEGETTE. No.
The CLERK. Ms. DeGette says nay.
Ms. Speier?
Ms. SPEIER. No.
The CLERK. Ms. Speier says nay.
Ms. DelBene?
Ms. DELBENE. No.

The CLERK. Ms. DelBene says nay.
Mrs. Watson Coleman?
Mrs. WATSON COLEMAN. No.
The CLERK. Ms. Watson Coleman says nay.
Madam Chair?
Mrs. BLACKBURN. Aye.
The CLERK. Madam Chair says aye.
Mrs. BLACKBURN. The clerk will report the tally.
The CLERK. Chairman Blackburn, on the vote there were eight "ayes" and five "nays."
Mrs. BLACKBURN. The motion to exclude is tabled.
At this time, I will begin the opening statement, and we will then move to our first panel of witnesses who have come to——
Ms. SCHAKOWSKY. Madam Chair, may I? I really want to ask at this point that your words be taken down regarding the assertion that staff "leaked documents to the entity," actually to StemExpress. These documents had already been given to witnesses and the press, and then were posted to your Web site. So I think your words need to be taken down. Accusing our staff of leaking that is not true, and those words should be taken down.
Mr. DUFFY. Madam Chair?
Mrs. BLACKBURN. Ms. Schakowsky, the staff had asked for the documents. They were shared—this was shared before they went to the Web site, and then they were released to the entity. And in order to take the comments down, the comments have to be personal in nature.
So with that, let's begin with our opening statements, and then we will receive our first panel of witnesses.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

As I was beginning earlier, I want to welcome all of our witnesses who are here today. I am going to introduce each of you later as we move forward with our testimony on the pricing of fetal tissue.
As part of my opening statement, I will present a narrative about the exhibits that today's hearing will discuss. I have said many times my hope is that both parties can work together on some things, and today's subject matter should be an opportunity to do so for a couple of reasons. First, at our initial hearing on bioethics and fetal tissue, all witnesses from both sides agreed that no one should profit from the sale of baby body parts. Nobody.
Second, the Democrats overwhelmingly supported a prohibition on profiting from fetal tissue sales during the 1993 passage of the National Institutes of Health Revitalization Act. Former Congressman Dingell passed this legislation out of the Energy and Commerce Committee, and former Congressman Henry Waxman amended the NIH bill on the floor to make clear that profiting from the sale of baby body parts was a crime.
Folks, these two Democrat leaders took the offense so seriously that they made profiting from the sale of fetal tissue punishable by a 10-year felony. They understood that unborn children do indeed have constitutional rights.

Now, there has been a lot of heated debate about the horrible videos that came out last year, but today's hearing will present business documents, invoices, marketing brochures, and management documents that reveal that one for-profit procurement business and several abortion clinics may have violated the intent of the statute and the Waxman prohibition passed overwhelmingly by a Democrat-controlled House.

We have invited former U.S. attorneys and others to help us understand this conduct in light of the existing statute. We look forward to working through this material in a thoughtful way, and I ask my colleagues on the other side to join in a productive discussion about the statute that your side passed.

Before I turn to introducing the documents, I want to call your attention to five posters that will help to visually follow the discussion. The first chart presents three entities involved in the business of selling the body parts. That chart depicts that the middleman, the procurement business, pays the abortion clinic for fetal tissue and is then paid by the researcher or the customer.

The second chart is a Web site screen grab from the procurement business of how to buy baby body parts online. Now there is a new Web site, and the baby body parts procurement business has been spun off to a new entity. That chart shows the drop-down box for every part imaginable: heart, eyes, scalp, liver, hands. Then you click on the next box and you pick the gestation period. Then you click and proceed to checkout to select your form of shipping. The third chart shows the daily tasks performed by the procurement business employee inside the abortion clinic.

Once the order is communicated, the procurement tech starts her work checking gestation periods, getting consent, procuring tissue, and sending to the customer. These are clear HIPAA violations. Our Democratic colleagues have voiced concerns over privacy throughout the investigation. I would hope, at a minimum, they will join us in condemning obvious violations of HIPAA, which was signed into law by President Clinton on August 21st of 1996.

The fourth chart summarizes several sample actual payments from the procurement business to the abortion clinic and from the customer to the procurement business. These are just samples for discussion today. They do not present the entire financial picture. And the fifth chart shows who bears the responsibility for the reasonable cost involved in the procurement and sale.

Next, I want to walk the witnesses through the exhibits. I know that all the lawyers in the room like to focus on every detail, and that is why you are here. But it is also important to understand the big picture of what the procurement business was trying to do, especially in light of the Waxman prohibitions against profiting from the sale of baby parts in the '93 NIH Revitalization Act.

Please turn to the B exhibits beginning with B2. This is the procurement company brochure that is handed out at national conferences where abortion clinic managers were in attendance. Notice it says "financially profitable," "fiscally rewards," "financial benefit to your clinic."

Look at Exhibit B3, which is a Web site screen grab of the procurement business. Once again, "Financially Profits ... while also

providing a financial benefit to ... your clinic." Evidently, the procurement business is not familiar with the Waxman prohibition.

Now, turn the page and look at Exhibits B4 and 5. The procurement business started in 2010 with three clinics. Two years, it was up to 30, and in 2 more years it had nearly 100. Further, they were negotiating a contract to have over 250 clinics by this year, but the comarketing negotiations with the national abortion trade organization fell apart just about the time the videos came out last year.

Now, you do not have to be a lawyer to see what is going on here. You put up a Web site that offers the parts imaginable, and why on earth would anybody ever need a baby scalp? Then you pick the gestation period and you check out. To offer that service, you need abortion clinics, a lot of abortion clinics. So you grow your number of clinics, and you offer the clinics money to sign up. You offer them financial benefit to join.

You tell the clinic that you will do all of the work, all of the items on the chart that show the workflow of the procurement technician. This does not sound to me like tissue donations for research. This sounds like someone who wants to make money, a lot of money, selling the baby body parts.

So I thank our witnesses for their generous time today. I welcome them.

[The prepared statement of Mrs. Blackburn follows:]

PREPARED STATEMENT OF HON. MARSHA BLACKBURN

Welcome to all the witnesses who are here today. I will be introducing each of you in a moment and I look forward to hearing your testimony on The Pricing of Fetal Tissue. As part of my opening statement, I will present a narrative about the exhibits that today's hearing will discuss. I have said many times, my hope is that both parties can work together on some things and today's subject matter should be a perfect opportunity to do so for two reasons:

First, at our initial hearing on Bioethics and Fetal Tissue, all witnesses from both sides agreed that no one should profit from the sale of baby body parts. No one.

Second, the Democrats overwhelmingly supported a prohibition on profiting from fetal tissue sales during the 1993 passage of the National Institutes of Health Revitalization Act.

Former Congressman Dingell passed out of the Energy and Commerce Committee and former Congressman Henry Waxman amended the NIH bill on the floor to make clear that profiting from the sale of baby body parts was a crime. Folks those two Democrat leaders took the offense so seriously that they made profiting from the sale of fetal tissue a ten year felony. They understood that unborn children do have constitutional rights.

Now there has been a lot of heated debate about the horrible videos that came out last year, but today's hearing will present business documents, invoices, marketing brochures, and management documents that reveal that one for profit Procurement Business and several abortion clinics may have violated the intent of the statute and the Waxman prohibition passed overwhelmingly by a Democrat controlled House. We have invited former U.S. Attorneys and others to help us understand this conduct in light of the existing statute. We look forward to working through this material in a thoughtful way and I ask my colleagues on the other side to join in a productive discussion about the statute your side passed.

Before I turn to introducing the documents, I want to call your attention to five posters that will help to visually follow the discussion.

(1) The first chart presents three entities involved in the business of selling baby body parts. That chart depicts that the middleman Procurement Business pays the Abortion Clinic for fetal tissue and is then paid by the Researcher or Customer.

(2) The next chart is a Web site screen grab from the Procurement Business of how to buy baby body parts online. That chart shows the drop down box for every part imaginable, heart, eyes, scalp, liver, hands—then you click on the next box and pick the gestation period of the part, then you click and proceed to checkout to select your form of shipping.

(3) The third chart shows the daily tasks performed by the Procurement Business employee inside the Abortion Clinic. Once the order is communicated, the Procurement Tech starts her work: checking gestation periods, getting consent, procuring tissue, and sending it to the Customer.

(4) The fourth chart summarizes several sample payments from the Procurement Business to the Abortion Clinic and from the Customer to the Procurement Business. These are just samples for our discussion today—they do not present the entire financial picture.

(5) And the fifth chart shows who bears the responsibility for the reasonable costs involved in the procurement and sale.

Next I want to walk the witnesses through the exhibits. I know that all the lawyers in the room like to focus on every detail and that is why you are here, but it is also important to understand the big picture of what the Procurement Business was trying to do—especially in light of the Waxman prohibitions against profiting from the sale of baby parts in the 1993 NIH revitalization Act.

Please turn to the B Exhibits beginning with B2.

This is the procurement company Brochure that it handed out at national conferences where Abortion Clinic managers were in attendance. Notice it says "financially profitable ... fiscally rewards ... financial benefit to your clinic."

Look at Exhibit B3, which is a WEb site screen grab of the Procurement Business. Once again "Financially Profitable ... while also providing a financial benefit to your own clinic."

Evidently the Procurement Business is not familiar with the Waxman prohibition.

Now turn the page and look at Exhibits B4 and B5.

The Procurement Business started in 2010 with 3 clinics. In 2 years it was up to 30 and in two more years it had nearly 100. Further, they were negotiating a contract to have over 250 clinics by this year, but the co-marketing negotiations with a national abortion trade organization fell apart about the time the videos came out last year.

Now you do not have to be a lawyer to see what's going on here. You put up a Web site that offers any baby body part imaginable—and why on earth do they need a baby scalp? Then you pick the gestation period and then check out.

To offer that service you need abortion clinics—a lot of abortion clinics—so you grow your number of clinics and you offer the clinics money to sign up—you offer them "financial benefit" to join in. You tell the clinic that you will do all the work—all the items on the chart that show the work flow of the procurement technician.

This does not sound to me like tissue donation for research—this sounds like someone who wants to make money, a lot of money, selling baby body parts.

Welcome to our witnesses. I look forward to hearing from each of you.

Mrs. BLACKBURN. And at this time, I yield 10 minutes to Ms. Schakowsky.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. From the outset, this investigation has not been an objective or fact-based search for the truth, but a political weapon to attack women's health care and lifesaving research and harass and intimidate those who provide these services. This was clear during our first hearing, where one of the witnesses invited by the Republicans drew a comparison between researchers who use fetal tissue and Nazi war criminal Dr. Josef Mengele, a comparison echoed by Chair Blackburn in her opening statement.

Another Republican witness testified that women who have abortions are "morally disqualified" from choosing to donate tissue for research purposes. For today's hearing, Republicans have again invited witnesses who believe that abortion should be illegal, that women should not be permitted or trusted to decide whether to carry a pregnancy to term. Some continue to declare that Planned Parenthood is selling fetal tissue, as you just heard, for profit, de-

spite the fact that three House committees, 12 States, and a Texas grand jury have already cleared the organization of wrongdoing.

These witnesses, like our Republican colleagues, endorse and rely upon the video allegations of anti-abortion extremist David Daleiden and his associates to support their inflammatory claims. Anyone who has been following the facts knows the truth. Mr. Daleiden's videos are not accurate or reliable, and they do not show the unlawful sale of fetal tissue, and we will argue today that the so-called exhibits do not make that case either.

A grand jury in Texas already put Mr. Daleiden to the test under oath, and he failed. That grand jury, instructed by the Republican Lieutenant Governor to investigate Planned Parenthood, instead indicted Daleiden for breaking the law through his efforts to entrap Planned Parenthood.

The district attorney handling the case refused to re-present it to another grand jury, explaining that "we must go where the evidence leads us." And then she explained, and I quote, "Anyone who pays attention knows that I'm pro-life. I believe abortion is wrong. But my personal belief does not relieve me of my obligation to follow the law." That standard should apply with equal force here.

There is no reason to believe that Daleiden—a proven liar when it comes to Planned Parenthood—would be any more truthful about anyone else involved in reproductive health care or fetal tissue research, yet instead of correcting the record on the Daleiden videos, the Chair continues to invoke them.

Today my Republican colleagues likely will claim that it is not just the videos—actually, the Chair has already claimed that. They may assert that documents that this Panel has received or that Republican staff have created show the need for further investigation, and this is also false.

Sixteen years ago, the Subcommittee on Health and Environment of the House Commerce Committee considered similar materials—16 years ago. That hearing titled "Fetal Tissue: Is it Being Sold in Violation of Federal Law?" featured a "fee for service schedule" showing amounts charged for types of tissue, "transaction logs" with charges for tissue on particular dates, and agreements between providers and procurement organizations.

And that hearing also featured an employee, Dean Alberty, who had worked at two tissue procurement organizations. The anti-abortion group "Life Dynamics" had filmed and released a video interview where—is it Alberty?—Alberty claimed to have witnessed fetuses "born alive," doctors changing procedures for donation purposes, and unlawful payment for fetal tissue, exactly the types of claims made in the Daleiden video.

In statements under oath, however, Alberty contradicted his inflammatory claims and admitted during the 2000 hearing that his sworn statements, not the remarks on the heavily edited video made by anti-abortion extremists, were the truth. The Department of Justice also investigated the allegations of unlawful profiteering that was at the heart of that hearing and concluded that no laws had been broken.

No one believes that companies should be allowed to profit by selling fetal tissue, and we firmly support the prohibition. However, just as it does for adult organ donation, the law expressly al-

lows reimbursement for cost. In fact, 42 U.S.C. 289g, the provision that we are focusing on today, is modeled on the National Organ Transplant Act, which similarly prohibits "valuable consideration" but allows reimbursement for costs associated with organ donation, which can be considerable.

Allegations regarding possible unlawful profit from adult organ transplantation would not result in a call to ban all organ donations, yet Republican lawmakers in the House want to ban fetal tissue donation and research altogether, something that some States have already done. Florida, for example, recently enacted a sweeping bill attacking women's health care and banning the donation of fetal tissue.

This is tragic for women and families on the Gulf Coast as summer approaches and researchers race to understand and solve the Zika virus. Despite Chair Blackburn's claim that Democrats are "exaggerating," she says, its importance, key studies have relied heavily on fetal tissue to increase our understanding of the Zika virus.

These bans have been proposed despite the fact that there still is no evidence of wrongdoing related to fetal tissue donation. Instead, the documents received by this Panel actually show that healthcare providers are losing money through programs that allow women to donate fetal tissue for research purposes.

This was not what Congress intended when it voted on a bipartisan basis to allow reimbursement of costs. It is absurd that even when they are losing money, providers are still attacked by those who appear to be motivated by their opposition to abortion, not the actual facts regarding fetal tissue donation. This Panel is a perfect example.

Over the course of the investigation, the Chair has targeted one clinic, one university, and one tissue procurement organization, all of whom were cooperating voluntarily before the Chair served them with unilateral subpoenas. The Panel has known since January that Southwestern Women's Options does not take any money for ensuring that women who want to donate tissue to the university can do so. And let me underscore that fact: No money is exchanged in connection with a woman's choice to donate fetal tissue to researchers at the University of New Mexico.

Already knowing this, the Chair served subpoenas and issued press releases tying them to what she repeatedly described as an investigation into the unlawful sale of "baby body parts," words we heard today.

As a result, the university and clinic have been subject to unwarranted accusations from State and Federal officials and additional targeted harassment from anti-abortion extremists. Is it any wonder that universities, clinics, and others are reluctant to hand over the names of their researchers, students, clinic personnel, and doctors, so that the Chair can amass a dangerous database of their names?

For its part, the tissue procurement company, StemExpress, already offered to have its procurement director explain its cost structure. The Chair ignored that offer and instead called this public hearing and invited witnesses who have no firsthand knowledge of the facts to opine about potential criminal misconduct.

On its own initiative, StemExpress has now submitted a letter to ensure that the Panel has the information needed to bring this investigation to an end. This investigation has never been—and has no promise of becoming—fair or fact-based. Our Republicans colleagues' disdain for the facts—and for women and their doctors—is putting researchers, doctors, and women at risk. It is time for Republican leadership to bring this investigation to an end.

I ask unanimous consent to have the April 18 letter from StemExpress included as part of the record for this hearing and yield back the balance of my time.

Mrs. BLACKBURN. The gentlelady yields back. On her UC request, we had already agreed to put that into the record.

At this time, I want to welcome our first panel. Senator Jeanne Shaheen is a U.S. Senator from New Hampshire. She is the only woman in U.S. history to be elected both a Governor and a U.S. Senator. Senator——

Ms. SCHAKOWSKY. Excuse me. Can I just say the letter I wanted inserted into the record is a different letter that we received from her yesterday, so if you could——

Mrs. BLACKBURN. So moved.

[The information appears at the conclusion of the hearing.]

Ms. SCHAKOWSKY. OK.

Mrs. BLACKBURN. So moved.

Ms. SCHAKOWSKY. Sorry.

Mrs. BLACKBURN. Senator Shaheen has served in the U.S. Senate since '09 and is a member of the Senate Committees on Armed Services, Foreign Relations, Appropriations, and is ranking member of the Small Business and Entrepreneurship Committee.

Senator Shaheen is a former small business owner and formerly served as the Director of Harvard University's Institute of Politics at the Kennedy School of Government. Welcome.

Senator Ben Sasse is a U.S. Senator from Nebraska. Senator Sasse comes to the Senate having spent the last 5 years as a college president, one of the youngest in the Nation. During the first and second terms of President George W. Bush, he worked in the Department of Justice and the Department of Homeland Security before becoming Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services. Welcome to you, Senator Sasse.

At this time, we will begin with Senator Shaheen for your 5-minute remarks, and we welcome you.

STATEMENT OF HON. JEANNE SHAHEEN, A UNITED STATES SENATOR FROM THE STATE OF NEW HAMPSHIRE

Mrs. SHAHEEN. Thank you very much, Chairwoman Blackburn and Ranking Member Schakowsky, members of the committee. I very much appreciate the opportunity to appear before you this morning, but I do so with great concern. I know you will hear from my colleague, Senator Sasse from Nebraska, and I respect his deeply held personal beliefs.

But if we want to have a civil discussion on this issue, we should begin with the facts. Already news articles today have called into question the validity of the exhibits that will be presented to the Panel. This committee's very existence was founded on the basis of

highly deceptive edited videos. These videos have since been proven to be misleading and false by multiple independent investigations across the country.

In January, after thorough investigations into the videos, a Texas grand jury cleared Planned Parenthood of any wrongdoing and indicted the individuals responsible for their creation. In fact, 12 other States have also cleared Planned Parenthood of any wrongdoing, and 8 additional States have declined to investigate, citing a lack of evidence.

I believe it is now time for the special investigations to end. And I would also like to point out that fetal tissue research has long had bipartisan support. In 1993, Congress passed the National Institutes of Health Revitalization Act, which permits fetal tissue research. That bill passed with overwhelming support, 94 to 4 in the Senate and 290 to 130 in the House.

And I think it is important to note that that bill was passed on recommendations of a blue ribbon panel convened under President Reagan, which was tasked with studying the ethics of fetal tissue research. Millions of people have benefitted from fetal tissue research. Vaccines for polio and rubella were developed as a result of research done on fetal tissue, and research on health issues that touch so many of us—Parkinson's disease, diabetes, HIV/AIDS, eye disorders and spinal cord injuries—have also benefitted from the 1993 law.

If it is the Panel's desire to change the law, obviously you, as legislators, are able to do that. But I believe it would be a grave error. Sadly, it is my belief that this Panel was formed with political motivations. There is very little real interest in an unbiased investigation to uncover facts related to women's health or research. Instead, I believe that this Panel serves as an opportunity for some to once again attack the healthcare providers who millions of women and families depend on.

In February, I joined with colleagues in both chambers to ask House and Senate leadership to disband this Panel and all other Congressional investigations that would undermine women's access to health care. Not only do I believe that this Panel is an inappropriate and wasteful misuse of Federal resources, but I am gravely concerned that it also puts researchers, providers, and patients across the country at risk.

Unfortunately, as a result of the political rhetoric surrounding this issue, we have seen violent acts and threats against women health providers and researchers across the country. And I am very sad to report that this fall, the same month that this panel was formed, a women's health clinic in Claremont, New Hampshire, was vandalized not once, but twice. The second attack caused so much damage that the clinic was forced to close for nearly six weeks, and this was a real disservice to the women, men, and families who rely on the full range of services that the clinic provides.

And, unfortunately, New Hampshire is not alone. After the release of the deceptive, highly edited videos, incidents of harassment against some health centers increased ninefold in just one month. I don't believe that today's hearing is a fact-based, objective investigation, but, rather, it is a taxpayer-funded political attack based on discredited evidence. I hope it will finally be time to move on.

And, Madam Chair, if I could apologize for the need to leave early and go back to a hearing. I appreciate, again, the opportunity to be here.

Thank you.

[The prepared statement of Mrs. Shaheen follows:]

Senator Jeanne Shaheen
House Select Investigative Committee
April 20, 2016
Testimony

Chairwoman Blackburn and Ranking Member Schakowsky, it is with great concern that I appear before you today.

I respect my colleague from Nebraska's deeply held personal beliefs.

But if we ever want to have a civil discussion on this issue, we should begin with the facts. Already, news articles today have called into question the validity of the exhibits that will be presented to the panel.

This panel's very existence was founded on the basis of highly deceptive, edited videos. These videos have since been proven to be misleading and false by multiple independent investigations across the country.

In January, after thorough investigations into the videos, a Texas grand jury cleared Planned Parenthood of any wrongdoing and indicted the individuals responsible for their creation. In fact, twelve other states have also cleared Planned Parenthood of any wrongdoing, and eight additional states have declined to investigate, citing a lack of evidence.

It is now time for the special investigations to end.

I'd like to make clear that fetal tissue research has long had bipartisan support. In 1993, Congress passed the National Institutes of Health Revitalization Act, which permits fetal tissue research. That bill passed with overwhelming support: 94-4 in the Senate and 290-130 in the House. And, it is important to note, that that bill was based on recommendations of a blue-ribbon panel convened under President Reagan which was tasked with studying the ethics of fetal tissue research.

Millions of people have benefitted from fetal tissue research. Vaccines for polio and rubella were developed as a result of research done on fetal tissue. And research on health issues that touch so many of us--- Parkinson's disease, diabetes, HIV/AIDS, eye disorders and spinal cord injury have also benefitted from the 1993 law.

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And New Hampshire is not alone. After the release of the deceptive, highly-edited videos, incidents of harassment against some health centers increased nine fold in just one month.

Today's hearing is not a fact-based objective investigation, but rather a taxpayer funded political attack based on manipulated and discredited evidence. It is time to move on.

Mrs. BLACKBURN. We thank you so much, and we know that you do have to leave and get back, that you all are having votes this morning, but thank you for the courtesy of your time and for waiting for us.

Senator Sasse, you are recognized for 5 minutes.

Ms. SCHAKOWSKY. Let me just thank Senator Shaheen as well. I appreciate your being here.

STATEMENT OF HON. BEN SASSE, A UNITED STATES SENATOR FROM THE STATE OF NEBRASKA

Mr. SASSE. Thank you, Madam Chairman. Good morning, Ranking Member. Thank you for including me. Many of us in the Senate, like many of you in the House, and, more importantly, like millions of Americans, watched with grief the video footage of abortion doctors and others discussing the sale of baby body parts for profit.

As a legislator, but more importantly as a father—I have three little kids, three precious ones, one of my little girls traveled with me from Nebraska to DC this week, and she is here with us today—more importantly, as a father, I support your investigation and your commitment to get to the bottom of what is going on here.

Let's begin by stating clearly that we should not have to be here today. The 1993 NIH Revitalization Act includes testimony where California Democrat Henry Waxman said, and I quote, "This amendment that I am offering would enact the most important safeguards to prevent any sale of fetal tissue for any purpose, not just for the purpose of research, any sale for any purpose. It would be abhorrent," Waxman continued, "to allow for the sale of fetal tissue and a market to be created for that sale."

Words are important. The report language and the floor debate created a very clear legislative intent that no one should profit—no one—from the sale of fetal tissue, yet here in today's documents and exhibits we see a business brochure and a Web site urging "Partner with us and improve the profitability of your clinic. Improve your bottom line. Be financially profitable." These are quotes.

That procurement business offers a payment per tissue to abortion clinics, and it offers to do all the work. That would appear to mean that the abortion clinic has no costs and it would, thus, appear to be precisely about profit as their marketing literature says.

Questions of profit and legality matter because we are talking about people. It matters whether or not procurement businesses broke the law. It matters whether or not abortion clinics are lining their pockets through the dismemberment and distribution of children, all while receiving tax dollars. It matters because we are talking about the tiny limbs of little babies that have dignity. They are broken, yet still precious, children of actual mothers and fathers.

As the committee's exhibits indicate, web pages exist where a customer can click on a dropdown box that lists every organ of a baby for sale. You can click on a brain, a heart, eyes, or a scalp. Then you select your gestation period, then you proceed to checkout and you decide the method of shipment.

We should pause to linger here. Our humanity should be repulsed. We should all be sad by this. In this committee room and

across the country, we will obviously have passionate disagreements and discussions about the legality, the justice, and the social implications of abortion policy. Like many in this room, like a majority of Nebraskans, and like a majority of Americans, I believe that every baby is precious and worthy of legal protection, even at earliest phases of development.

I am unashamedly pro-life, but I also understand that many others disagree on abortion policy. Our disagreements on abortion will sometimes be heated, but wherever possible we should be looking for consensus, and here, on this basic reality, we can and should agree babies are not the sum of their body parts. Babies are not meant to be bought, and babies are not meant to be sold. Babies are just that; they are babies. They are meant to be welcomed and rejoiced over, held and nurtured.

Outside of our Congressional responsibilities here, many of us do in fact welcome, hold, and nurture little children. We adopt and we foster and we mentor them. We offer hope, support, and encouragement to their parents. Madam Chairman, your work can and does transcend politics.

I appreciate also your concern with children born alive inside abortion clinics and with the treatment that they receive. When I think of all the survivors of abortion and I think about your investigation into the sale of baby body parts for profit, it makes born-alive legislation all the more important. The Born-Alive Abortion Survivors Protection Act has already passed the House by a bipartisan vote of 248 to 177, and I have had the privilege of introducing the companion legislation in the Senate, and I invite my Senate colleagues on both sides of the aisle to be working together to pass this bill in our chamber.

This law would simply ensure that babies who survive abortions get a fighting chance by requiring medical attention that is equivalent to what would be offered to any other premature baby born at the same stage. No life is disposable. No child deserves to have her life ended cold and alone, struggling for breath outside the womb in an abortion clinic.

We Americans frequently cheer for the vulnerable, we fight for the minority, we protect the powerless against the powerful, and baby girls and boys are fighting for their lives. I encourage my colleagues to fight for them and to support Senate 2066, the Born-Alive Abortion Survivors Protection Act.

Madam Chairman, we look forward to monitoring the progress of your investigation, and thank you for including me in this hearing.

[The prepared statement of Mr. Sasse follows:]

Prepared Testimony of Senator Ben Sasse (NE)

Before the U.S. House of Representatives Committee on Energy and Commerce

Select Panel on Infant Lives

"The Pricing of Fetal Tissue"

April 20, 2016

Good Morning Madam Chairman,

Thank you for the opportunity to testify before the Select Investigative Panel on Infant Lives. Many of us in the Senate, like you in the House, and more importantly millions of Americans watched with grief and horror the video footage of abortion clinic doctors and others discussing the sale of baby body parts for profit. As a legislator, but more importantly as the father of three precious little ones, I support your investigation and commitment to get to the bottom of what is going on.

Let's begin by stating clearly that we should not have to be here today. When Congress passed the 1993 National Institutes of Health Revitalization Act, California Democrat Henry Waxman appropriately noted:

> This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any purpose, just not for the purpose of research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.[1]

Words are important. The Report language for the NIH Revitalization Act and the floor debate created a very clear legislative intent that "no one should profit from the sale of fetal tissue."

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[1]CONG REC. H1131 comments of Mr. Waxman.

Yet here, in today's documents and exhibits, we see the following: A procurement business brochure and web site that urges "partner with us and improve the profitability of your clinic . . . improve your clinic's bottom line . . . financially profitable." That procurement business offers a payment per tissue to abortion clinics and offers to do all the work. The Abortion Clinic appears to have no costs. It appears to be precisely about profit.

Questions of profit and legality *matter* because we are talking about *people.*

It *matters* whether or not procurement businesses broke the law.

It *matters* whether or not abortion clinics line their pockets through the dismemberment and distribution of children—all while receiving tax dollars.

It matters because we are talking about the tiny limbs of babies with dignity—the broken yet still precious children of mothers and fathers.

As the committee's exhibits indicate—web pages exist where a customer can click on a drop-down box listing every organ in the baby's body for sale. Just click on a brain, a heart, eyes, or scalp and then select your gestation period and then proceed to check out and select your shipment method. We should pause to linger here... and our humanity should be repulsed.

In this committee room, and across the country, we will have passionate discussions and disagreements over the legality, the justice, and the social implications of abortion policy.

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Babies are just that—babies. They're meant to be welcomed and rejoiced over, held and nurtured.

Outside of our Congressional responsibilities here, many of us do welcome, hold and nurture children—we adopt, foster, and mentor them and offer hope, support, and encouragement to their parents.

Madam Chairman, your work can and does transcend politics.

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The Born-Alive Abortion Survivors Protection Act has already passed the U.S. House of Representatives by bipartisan vote of 248 to 177.

I had the privilege of introducing the Senate companion legislation and invite my colleagues in the Senate—on both sides of the aisle—to work together and pass this bill.

This law would simply ensure that babies who survive abortions get a fighting chance by requiring medical attention that would be offered to any other premature baby at the same age.

No life is disposable. No child deserves to have her life ended cold and alone—struggling for breath—in an abortion clinic.

We Americans frequently cheer for the vulnerable. We fight for the minority. We protect the powerless from the powerful. Baby girls and boys are fighting for their lives.

I encourage my colleagues to fight for them and support S. 2066, the Born-Alive Abortion Survivors Protection Act.

Madam Chairman, we look forward to monitoring the progress of this investigation, and thank you again for including me in this important hearing.

Mrs. BLACKBURN. Thank you, Senator Sasse. We appreciate your time. We are sorry for our delay. And we know that you have to scoot back across to the Senate for votes, but thank you for your time.

At this time, I would like to call forward our second panel. And as they move forward to be seated on the panel, I will move forward with introducing this panel to our audience, so that we can move forward expeditiously.

Fay Clayton is an attorney with Robinson Curley & Clayton. Ms. Clayton practices civil litigation for a wide range of clients from major corporations to individuals in cases involving fraud, RICO securities, general commercial matters, contract disputes, officer and director liability, and shareholder and partnership concerns.

Mr. Robert Raben served as Assistant Attorney General for Legislative Affairs with the U.S. Department of Justice, where he drove Attorney General Janet Reno's legislative initiatives and handled the political challenges of Congressional oversight of the department. He founded The Raben Group, a public policy consulting organization, in 2002 and continues to serve as president. He is a graduate of the Wharton School and the New York University Law School.

Mr. Brian Lennon served as a Federal prosecutor in Michigan and Virginia for 15 years and a trial attorney for the U.S. Department of Justice's Civil Division. As the Deputy Chief of the Criminal Division for the U.S. Attorney's Office in the Western District of Michigan, Brian supervised the healthcare fraud and computer-related crimes units, among others.

He also spent 4 1A½ years as a judge advocate for the U.S. Marine Corps, handling both civil and criminal matters. Now in private practice with Warner Norcross and Judd, he specializes in criminal defense, particularly healthcare fraud and other white-collar and drug offenses, corporate internal investigations, and compliance matters.

Mr. Michael Norton served as U.S. Attorney for Colorado from 1988 to '93. He was appointed by President Reagan and reappointed by President George H.W. Bush. Mr. Norton has been practicing law since 1976 and is admitted to the bars in the States of Colorado and Virginia as well as Washington, DC.

Catherine Glenn Foster is an associate scholar with the Charlotte Lozier Institute, where she authors research papers on science, medicine, and research in the service of human life. She was formerly an attorney with Alliance Defending Freedom and is a graduate of Georgetown University Law Center.

Kenneth Sukhia was appointed U.S. Attorney for the Northern District of Florida by President George H.W. Bush and has served as litigation counsel to numerous corporations and officials. Mr. Sukhia has also served as law clerk at the Florida Supreme Court and the U.S. Court of Appeals and as a senior partner in one of Florida's oldest and largest statewide firms. He began his own firm, the Sukhia Law Group, in the Florida State capital in 2008.

You are aware that the Select Investigative Panel is holding an investigative hearing and that we will take your testimony under oath. Do you have any objection to testifying under oath?

OK. The Chair then advises you that, under the rules of the House Committee on Energy and Commerce, you are entitled to be advised by counsel. Do you desire to be advised by counsel for today's hearing?

OK. In that case, will you please rise and raise your hand, and I will swear you in.

[Witnesses sworn.]

Mrs. BLACKBURN. Thank you. You are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the U.S. Code.

You will each give a 5-minute summary of your written statement. Ms. Clayton, we will begin the testimony with you, and you are recognized for 5 minutes.

STATEMENTS OF FAY CLAYTON, SENIOR PARTNER AND FOUNDING SHAREHOLDER, ROBINSON CURLEY & CLAYTON, P.C.; ROBERT RABEN, PRESIDENT AND FOUNDER, THE RABEN GROUP; BRIAN PATRICK LENNON, PARTNER, WARNER NORCROSS & JUDD; MICHAEL J. NORTON, ATTORNEY AND COUNSELOR AT LAW, THOMAS N. SCHEFFEL & ASSOCIATES, P.C.; CATHERINE GLENN FOSTER, ASSOCIATE SCHOLAR, CHARLOTTE LOZIER INSTITUTE, CEO AND GENERAL COUNSEL, SOUND LEGAL; AND KENNETH W. SUKHIA, SENIOR PARTNER, SUKHIA LAW GROUP

STATEMENT OF FAY CLAYTON

Ms. CLAYTON. Thank you, Madam Chair. I have been a corporate litigator since 1978, and I am here today despite a family medical situation for two reasons. One is that women's reproductive health and medical research are being threatened by these hearings. The second reason is that I have instructive experience to share with this Panel on the topic that you are considering here.

Sixteen years ago, a client of mine, Anatomical Gift Foundation, a nonprofit corporation that provided donated tissue to medical researchers in hopes of curing the diseases, including the ones Senator Shaheen mentioned earlier—that nonprofit was falsely accused by Life Dynamics, the anti-abortion group Congresswoman Schakowsky mentioned, accused of selling fetal tissue.

These baseless charges were made in a videotape sent by Life Dynamics to Congress, and in that video the person making the accusations was anonymous. As it happened, an employee of Anatomical Gift Foundation, my client, had gone to work for another company in violation of his contract. AGF hired me to sue. That man's name was Dean Alberty.

In Alberty's deposition, which was under oath, like all of us today, but unlike what he said in the videotape—the videotape that Life Dynamics had sent to Congress—Alberty admitted that he was the person in that video, and he admitted that what he had said in that video was fictional.

He testified that he told those lies because Life Dynamics had paid him to, and he said, "I needed the money." He had repeated those falsehoods on TV's "20/20," but he knew better than to lie under oath when I deposed him, where the penalties of perjury, as the Chair acknowledged, do arise.

Those of you who were here in the year 2000 may recall the humiliation that certain members of the House Committee suffered when their star witness, Dean Alberty, went up in flames and admitted that that much-touted video had been fabricated. Those House hearings established that my client had done nothing wrong, that fetal tissue wasn't for sale at all, and that anti-abortion zealots—Life Dynamics—had foisted a false witness on Congress. What was for sale wasn't fetal tissue; it was a phony witness statement, and it had been bought and paid for by anti-abortion extremists.

I find it curious, given the not-so-distant history of the strikingly similar scenario, that this Panel has not demanded sworn testimony of the accusers, the latest batch of anti-abortion accusers, as you have asked of us, Chair Blackburn. You haven't asked for that, haven't asked them to go under oath, and that seems strange to me, particularly when they come up with such a similar tale about the so-called sale of fetal tissue, which again is a lie.

This suggests to me that someone is afraid to put David Daleiden and his star witness, Holly O'Donnell, under oath because, as we saw with the Dean Alberty fiasco, when penalties of perjury attach, sometimes instead of fiction the actual truth comes out. We know Daleiden and his crew doctored videos to the point that the Federal judge blocked the release of further tapes because they were fraudulent.

Another fact we know about them comes from the Los Angeles Times' examination of Daleiden's unedited videos. They show Daleiden coaching and manipulating the testimony of Holly O'Donnell, whose video interview, by the way, looks more like playacting than any genuine emotion. Without cross-examination of Daleiden and his crew under oath, we have no way of knowing what he offered or said to Ms. O'Donnell when his camera was not running.

And in Texas, when Daleiden went before a grand jury convened for the express purpose of prosecuting Planned Parenthood, the grand jury did something very different. It didn't indict Planned Parenthood, it indicted Daleiden for falsehoods. And the Texas grand jury found, of course, that Planned Parenthood had done nothing wrong.

For nearly four decades, I have been representing corporations and individuals in business litigation, and I have to say there is no bigger tell about the veracity of an accusation than when the person who is making the accusation will not stand by his or her accusation under oath.

As Alberty told the House committee in the year 2000, "When I was under oath, I told the truth. Anything I said in the video, when I was not under oath, that's a different story." So I have to ask, is this Panel looking for the truth or for another story? A real inquiry would start with sworn testimony from Daleiden and O'Donnell, and that would be true even if the doctored videotapes didn't have so much in common with the deceitful tapes that the abortion opponents, including Life Dynamics, staged 16 years ago.

This Panel's failure to allow cross-examination of Daleiden and his cohorts sends the message loud and clear that those stories would not hold up under penalty of perjury any more than the

baseless slurs Dean Alberty made back in the year 2000 when Life Dynamics bought and paid for his testimony.

And, by the way, you know, Crutcher is one of the trainers of Daleiden.

It just strikes me as inexcusable that the Panel has been using its subpoena power to compel testimony from healthcare providers and medical researchers who have far better things to do with their time—like providing health care, working to cure disease—than Daleiden and his crew.

Mrs. BLACKBURN. Ms. Clayton?

Ms. CLAYTON. I just ask that until and unless this Panel puts Daleiden and O'Donnell under oath, and tries to get to the bottom of what they did, that these proceedings be terminated and our elected officials be allowed to return to doing the people's business.

Thank you.

[The prepared testimony of Ms. Clayton follows:]

Testimony of Fay Clayton
Senior Partner and Founding Shareholder
Robinson Curley & Clayton, P.C.

Hearing on
"The Pricing of Fetal Tissue"

Before the Select Investigative Panel
of the Committee on Energy and Commerce
U.S. House of Representatives

April 20, 2016

I come to testify, in my personal capacity, despite having been out of town the past three weeks with a family health situation, because my family and I strongly support women's reproductive health and medical research, both of which are being threatened by these proceedings. Like millions of women in this country, for many decades I and members of my family have turned to Planned Parenthood for health care. I also have instructive experience to share relating to the issues before the Select Panel.

I've practiced law in Chicago since 1978, where I've focused on corporate litigation. Back in 2000, I represented the Anatomical Gift Foundation, a nonprofit corporation that provided donated tissue to medical researchers. An anti-abortion group, Life Dynamics, had released a supposedly damning expose accusing that foundation of selling fetal tissue, which is illegal. The video featured a former AGF employee – whose identity was disguised – saying he'd seen all manner of horrible and unlawful practices. Life Dynamics aggressively promoted the video to the media and elected officials. 20/20 ran a sensational television segment, and the House health and environment subcommittee convened hearings. AGF was demonized and threatened with violence.

As it happened, an AGF employee had recently quit and gone to work for another company in violation of his contract, and AGF hired me to represent the company. That former employee's name was Dean Alberti. In his deposition – which was, of course, taken under oath – Mr. Alberti admitted that he was the man in the Life Dynamics video and that his key statements in that video were fiction. He admitted making those false statements because Life Dynamics had paid him to do it, and he needed the money. Mr. Alberti repeated his fabricated charges on 20/20; but he knew better than to lie under oath when I deposed him.

Those who were here in 2000 likely recall what happened next. Republicans on that House subcommittee saw their star witness, Dean Alberti, go up in flames as he admitted what he'd said in the much-touted video was false. The hearings established that my client, AGF, had done nothing wrong, and that fetal tissue wasn't "for sale" at all. What was for sale was phony witness testimony, bought and paid for by opponents of abortion.

All indications are that the accusations in the "sting" videos about Planned Parenthood wouldn't fare any better if this Select Panel subpoenaed their producer, David Daleiden, and his star witness, Holly O'Donnell, to testify under oath. As we know, when Mr. Daleiden went under oath before a grand jury, which was demanded by an openly anti-abortion lieutenant governor to investigate Planned Parenthood, the Texas grand jury not only exonerated Planned Parenthood, it indicted Mr. Daleiden.

We also know that a federal judge, the Honorable William Orrick of the United States District Court for the Northern District of California, enjoined Mr. Daleiden from releasing additional heavily doctored videos because viewing all the footage in context – as Judge Orrick did – revealed Daleiden's edited versions were "fraudulent."

Also, as we know from an investigation by the *Los Angeles Times*, the unedited videos show Mr. Daleiden extensively coaching and manipulating the testimony of Ms. O'Donnell. Her video interview looks more like a theatrical performance than a display of true emotion. Without placing them under oath and subjecting them to cross-examination, we have no way of knowing what Mr. Daleiden said or offered to Ms. O'Donnell when his cameras weren't running.

Any investigation worthy of the name would begin with taking sworn testimony from Mr. Daleiden, Ms. O'Donnell, and their associates. That would be the case even without the striking similarities to the AGF episode sixteen years ago.

I've represented corporations and individuals in business litigation nearly four decades, including companies that were accused of wrongdoing by their employees and employees who leveled such accusations. There is no bigger tell about the veracity of an accusation than when the accuser won't stand by his or her statement under oath. As *Roll Call* quoted Dean Alberti saying in 2000, "When I was under oath, I told the truth. Anything I said in the video when I was not under oath, that's a different story."

The Select Panel's failure to subpoena the accusers here, or their failure to attend voluntarily, sends the message that these accusers' stories wouldn't hold up any better under penalty of perjury than the baseless slurs made by Life Dynamics and Dean Alberti in 2000. The fact that the Select Panel has been using its subpoena power to compel testimony from health care providers and medical researchers – who have better things to do with their time than Mr. Daleiden does – suggests the Panel is not genuinely interested in public policy at all. Unless this Select Panel is willing to put Mr. Daleiden and his associates under oath and get to the bottom of what *they* did, it should terminate these proceedings now and return to doing the people's business.

Mrs. BLACKBURN. Thank you, Ms. Clayton.
Mr. Raben?

STATEMENT OF ROBERT RABEN

Mr. RABEN. Good morning, Chair Blackburn, Ranking Member Schakowsky, members of the committee, thank you so much for having me this morning. My name is Robert Raben. I am in private practice. Over the years, I have served as counsel to the House Judiciary Committee and was confirmed as Assistant Attorney General for the Office of Legislative Affairs at the Department of Justice.

In 1999, as I was watching you this morning and the decorum and kindness with which you obviously run this committee, I was reminded that my then-chair—I was Democratic counsel, but the chair of our committee—Henry Hyde, walked across the Capitol to testify for my nomination, and what a wonderful day that was and how much I miss him and appreciated him.

I have taught law, practiced at a large law firm, and clerked after law school. I deeply appreciate the law and this committee's attention to it.

For over 20 years, my work has involved the representation of people and organizations before the Congressional and executive branch. I give this testimony today as someone who has experienced both sides of advocacy and representation around investigations of all forms. This committee has asked us to opine on the questions of whether the current legislative language adequately prevents profiteering in the sale of fetal tissue and the parameters around what constitutes a sale of profit of fetal tissue.

In 2000, in my capacity as Assistant Attorney General for the Office of Legislative Affairs at the Department of Justice, I was called upon to respond to almost identical concerns expressed by Members of the Congress regarding the alleged transfer of fetal tissue for profit. On March 9, 2000, I communicated with Congress by signed letter a willingness to investigate and learn further about credible claims and allegations.

While I don't have specific recollection of further oral conversations within the Department subsequent to that written communication, I know from the public record that in July of 2000, Acting Kansas U.S. Attorney Jim Flory decided, after a thorough review of the issues involved, that there were no violations of Federal statutes, thereby announcing the closure of a thorough investigation into related facts. That is a matter of public record. I also recalled yesterday a second investigation from the Colorado U.S. Attorney and FBI that was similarly closed.

We are today witnessing virtually identical allegations. While I am unaware as to whether DOJ or the FBI presently have ongoing inquiries into the factual allegations, it is significant to note that 12 States have affirmatively looked into related matters and declined to pursue any charge. An additional eight States have affirmatively declined to even investigate.

Given the importance that some people have about deferring to the States, I would like to just read into the record the 12 States that have affirmatively said they have investigated and decided not to pursue charges around related allegations: Florida, Georgia, In-

diana, Kansas, Massachusetts, Michigan, Missouri, Ohio, Pennsylvania, South Dakota, Texas, and Washington.

Innumerable reasons exist as to why Federal law enforcement has little record of indictment under the existing language, which may include the dearth of actual profiteering in fact, the deference to State law enforcement authorities which are certainly capable of determining the same predicate, past failed attempts to establish wrongdoing, or, paramount in this area, a lack of credibility of those presenting facts to the law enforcement officials.

Of the ultimate question on which this committee is presently engaged, whether or not the existing statute merits either change or more rigorous enforcement, I believe that the statute is sound and fully addresses its intended aims, as important today as it was when it passed with overwhelming bipartisan majorities in 1993.

The statute, a considered bipartisan judgment of Congress, was meant to address profiteering from the sale of fetal tissue. There is no evidence of an outbreak of such behavior in this Nation. Further, I am confident that any acts of intentional misbehavior would be investigated and punished by law enforcement, both Federal and State.

Thank you for having me.

[The prepared testimony of Mr. Raben follows:]

THERABENGROUP

Tuesday, April 19th 2016

Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Honorable Chairman and Members of the Committee,

My name is Robert Raben. Now in private practice, over the years I have served as counsel to the House Judiciary Committee, and was the confirmed Assistant Attorney General for the Office of Legislative Affairs at the Department of Justice from 1999 to 2001. I have taught law, practiced at a large law firm, and clerked after law school. I deeply appreciate the law, and this Committee's attention to it.

For over twenty years, my work has involved the representation of people and organizations before the Congressional and executive branch. I give this testimony as someone who has experienced both sides of advocacy and representation around investigations.

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In 2000, in my capacity as Assistant Attorney General for the Office of Legislative Affairs at the Department of Justice, I was called upon to respond to almost identical concerns expressed by members of the Congress regarding the alleged transfer of fetal tissue for profit. On March 9th 2000, I communicated with Congress a willingness to investigate and learn further about credible claims and allegations. While I have no recollection of further oral conversations within the Department

subsequent to that communication, I know from the public record that in July 2008, Acting Kansas US Attorney Jim Flory decided "after a thorough review of the issues involved," that there were no violations of federal statutes, thereby announcing the closure of a thorough investigation into related facts. That is a matter of public record. We are today witnessing virtually identical allegations.

While I am unaware as to whether DOJ or the FBI presently have ongoing inquiries into the factual allegations, it is significant to note that twelve states have affirmatively looked into related matters and declined to pursue any charge, and an additional eight states have affirmatively declined to even investigate.

Innumerable reasons exist as to why federal law enforcement has little record of indictment under the existing language, which may include: the dearth of actual profiteering in fact, the deference to state law enforcement authorities which are certainly capable of determining the same predicate, past failed attempts to establish wrongdoing, or a lack of credibility of those presenting facts to the law enforcement officials.

Of the ultimate question on which this Committee is presently engaged, whether or not the existing statute merits either change or more rigorous enforcement, I believe that the statute is sound and fully addresses its intended aims. The statute, a considered bipartisan judgment of Congress, was meant to address profiteering from the sale of fetal tissue. There is no evidence of an outbreak of such behavior in this Nation.Further, I am confident that any acts of intentional misbehavior would be investigated and punished by law enforcement, both Federal and State .

Yours respectfully,

Robert Raben

Mrs. BLACKBURN. Thank you, Mr. Raben.
Mr. Lennon, you are recognized for 5 minutes.

STATEMENT OF BRIAN PATRICK LENNON

Mr. LENNON. Chairman Blackburn, Ranking Member Schakowsky, and distinguished members of this Panel, thank you for the opportunity to speak to you today about the pricing of fetal tissue. I am currently a partner at the law firm of Warner Norcross and Judd in Grand Rapids, Michigan. For 13 years before entering private practice, I was an Assistant U.S. Attorney in the Western District of Michigan.

I am not a medical ethicist or a theologian. I do not represent any advocacy group on either side of the life versus reproductive rights debate, and I am not here to advocate for any change in Federal legislation.

But as a former Federal prosecutor, and now criminal defense counsel, I hope to provide some value to this Panel through objective legal analysis of the exhibits to determine whether the abortion clinics and/or the procurement business identified in the exhibits violated the statute.

Based on my review of the exhibits—and I looked at this as if an agent had showed up at my office on any work day with these exhibits and asked me to examine them—but based on that review, I believe a competent and ethical Federal prosecutor could establish probable cause that both the abortion clinics and the procurement businesses violated the statute, aided and abetted one another in violating the statute, and likely conspired together to violate the statute.

In fact, for five of the six elements of the substantive offense, in my opinion, there is proof beyond a reasonable doubt. The only element where investigation is needed—and that would include, I believe, forensic accounting and analysis thereof—is whether the payments made by the research institutions that ultimately receive the human tissue to the procurement businesses were a valuable consideration or, alternatively, reasonable payments associated with the specific allowable services in the statute.

With respect to the abortion clinics, in my opinion, the proof is more clearly established that the compensation they receive from the procurement business, a price per tissue payment, is indeed valuable consideration, as none of the identified services excluded from the definition were provided by the clinics.

Now, prosecutors and jurors clearly prefer to define and establish elements of the offense. Five of the six elements of that offense are both clearly defined and established through the exhibits. As for the final element, valuable consideration, that element and those proofs are admittedly more nuanced.

The statute itself defines valuable consideration by describing what it is not. It does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. If valuable consideration is payment for something other than this exhaustive list of delineated services, this element is also established.

As for the abortion clinics, the marketing materials that I have reviewed clearly state that there is a financial profit from this part-

nership. Several of the exhibits indicate the procurement business pays per the tissue, not a reasonable payment for the listed services. Therefore, the exhibits indicate, in my opinion, that these services provided by the procurement business through their embedded technicians, and not the abortion clinics, therefore, that these payments appear to be a valuable consideration. Indeed, they could be profits.

As for the procurement business, it is my opinion that a much deeper analysis of the company's financials is necessary in order to establish the valuable consideration element beyond a reasonable doubt. Because the businesses do in fact incur costs associated with these delineated services, a forensic accounting would be essential to breaking down the company's financials. Just looking at the growth and looking at their revenue doesn't tell you whether they are profiting. And if they are profiting, in my opinion, they violated the law.

I think there are some other theories here, although, that I think a prosecutor would pursue that may be more important in looking at the potential criminality of the businesses, the procurement businesses, and those are aiding and abetting and conspiracy.

Based on my limited review of the exhibits reviewed and the strength of the substantive case against the abortion clinic, pursuing an aiding and abetting or conspiracy count against the procurement business, rather than a substantive count, may be a stronger theory of culpability.

As I conclude, I would just say that I believe Federal prosecutors take pride in protecting the most vulnerable among us. The ones I proudly served with in the Western District of Michigan did not shy away from the tough cases, and they put their personal politics aside when asked to evaluate cases for prosecution.

Evidence, or the lack thereof, not politics, should determine whether a U.S. attorney impanels a grand jury to investigate abortion clinics and human fetal businesses in their district.

Again, I thank you, Chairman Blackburn and Ranking Member Schakowsky, and the members for allowing me to testify today, and I welcome your questions.

[The prepared testimony of Mr. Lennon follows:]

Testimony of Brian Patrick Lennon
Former Assistant United States Attorney – WD Michigan

April 20, 2016

Introduction

Chairman Blackburn, Ranking Member Schakowsky, and Distinguished Members of the Select Investigative Panel, thank you for the opportunity to speak with you today about the pricing of fetal tissue. As you will see from the curriculum vitae I submitted with this written testimony, I am currently a partner at the law firm of Warner Norcross & Judd in Grand Rapids, Michigan, where I am the Chair of the firm's White Collar Crime & Internal Investigations Practice Group. For 13 years before entering private practice I was an Assistant U.S. Attorney in the Western District of Michigan, where from 2001 to 2005 I served as deputy chief of the criminal division. As a former federal prosecutor, I appreciate the opportunity to review the exhibits provided to me over the weekend by committee staff, and to provide legal analysis and opinion as to whether abortion clinics and human fetal tissue procurement businesses identified in the exhibits may have violated federal law.

I am neither a medical ethicist nor theologian. I do not currently represent, nor have I ever represented, any advocacy group on either side of the life vs. reproductive rights debate. I am not here today to advocate for any change in federal legislation. But as a former federal prosecutor, and presently a criminal defense counsel who represents both individuals and corporations in state courts throughout Michigan and federal courts throughout the United States, I hope to provide some value to this investigative panel through objective analysis of the documents provided to me by members of your staff, as well as related, publically available information, to determine whether the abortion clinics and/or the human fetal tissue procurement

business as identified in the exhibits have violated Title 42, Section 289g-2 of the United States Code.

Based on my review of the exhibits, a competent, ethical federal prosecutor could establish probable cause that both the abortion clinics and the procurement business violated the statute (42 U.S.C. § 289g-2), aided and abetted one another in violating the statute (18 U.S.C. § 2), and likely conspired together to violate the statute (18 U.S.C. § 371). In fact, for five of the six elements of the substantive offense, there is proof beyond a reasonable that both the abortion clinics and the procurement businesses violated the statute. The only element, in my opinion, where further investigation, including forensic accounting and analysis is necessary is on whether the payments made by the research institutions that ultimately received the human fetal tissue, to the procurement businesses, were "valuable consideration" or, alternatively, "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue." *See* 42 U.S.C. § 289g-2(e)(3). With respect to the abortion clinics, in my opinion, the proofs more clearly establish that the compensation they receive from the procurement businesses – a price per tissue payment -- was valuable consideration, as none of the identified services excluded from the definition of "valuable consideration" were provided by the abortion clinics.

Caveat

As a federal prosecutor, I never prosecuted any individual or entity for this crime, so my testimony today is not based on any previous case experience. Indeed, my rudimentary research over the weekend before today's hearing failed to identify a single published or unpublished criminal case, in any federal circuit, so I suspect that no U.S. Attorney's Office has prosecuted such a case.

Elements of the Offense – 42 U.S.C. § 289g-2

Before reviewing the exhibits, I began as I would with any criminal case evaluation, by reviewing the statute and identifying the elements of the offense. I identified the following six elements: (1) any person; (2) who knowingly; (3) acquires, receives or otherwise transfers; (4) human fetal tissue; (5) for valuable consideration; and (6) the transfer affects interstate commerce, violates the statute.

a. Any Person

"Person" is not defined in the definitions section of the statute. *See* 42 U.S.C. § 289g-2(e). The Dictionary Act, however, provides that "[i]n determining the meaning of any Act of Congress, unless the context indicates otherwise. . . the words 'person' or 'whoever' include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." *See* 1 U.S.C. § 1. Under federal law, corporations and most other legal entities may be criminally liable for the crimes of their employees and agents.

b. Knowingly

This is a general intent crime. As a general rule when the term *knowingly* is used in an indictment, it means the defendant knew (or was aware) of what he or she was going to do and, subject to that knowledge, engaged in the act for which he or she has been charged.

c. Acquires, Receives or Otherwise Transfers

This element is self-explanatory. Moreover, since it is set forth in the disjunctive ("or"), rather than the conjunctive ("and"), the prosecutor only needs to establish that a defendant did one of the three acts -- acquired, received or otherwise transferred the human fetal tissue at issue.

d. Human Fetal Tissue

This is defined in section 289g-1(g) as "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth."

e. Valuable Consideration.

Section 289g-2(e)(3) defines "valuable consideration" by describing what it is not. It "does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control or storage of human fetal tissue." There are several statutes that similarly define "valuable consideration." These include 42 U.S.C. § 274e, pertaining to the sale of human organs, and the Uniform Anatomical Gift Act, as well as several state statutes -- specifically, Wisconsin, Nevada, Colorado & Nebraska. If "valuable consideration" is every payment for something other than this exhaustive list of delineated services, then any access, finder, or referral fee; payment for advertising or marketing; bonuses paid for more desired organs or tissues, or for increased volume; and any profit could meet this element of the statute.

f. Transfer Affects Interstate Commerce.

Here the statute provides that the definition of "interstate commerce" is the meaning set forth in 21 U.S.C. § 321, which "means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body." On this point the statute is clear – the human fetal tissue must affect interstate commerce in order for the statute to be violated. Consequently, for any human fetal tissue procured in California and sent by the procurement business to a California research facility, there would be no violation of 42 U.S.C. § 289g-2. This is analogous to a situation where a convicted felon in the Commonwealth of Massachusetts possesses a firearm made in Massachusetts. While it may be illegal to do so under

Massachusetts law, it would not be a violation of 18 U.S.C. § 922g (the federal felon-in-possession statute), because the government would be unable to prove the interstate nexus element of the offense; that is, that the firearm crossed state lines. Intrastate transfers of any procured human fetal tissue -- even if knowingly acquired, received or otherwise transferred for profit -- does not appear to violate the statute. Basically, if the human fetal tissue at issue crosses state lines, then this element is met.

The Pricing of Fetal Tissue is Key to Determining "Valuable Consideration"

Prosecutors and juries prefer clearly defined and established elements of an offense. There is no dispute that five of the six elements of the offense are clearly defined. Moreover, based on the exhibits provided, in my opinion, a competent and ethical federal prosecutor could establish five of the six elements of the offense beyond a reasonable doubt. Specifically, no one can dispute that: (1) individuals and both business entities; (2) knowingly; (3) acquired, received, or otherwise transferred; (4) human fetal tissue; (5) which crossed states lines. As for the final element, whether individuals or persons received "valuable consideration," for doing this, that element and those proofs are more nuanced.

Before identifying the key exhibits and points that establish "valuable consideration," there are a number of assumptions I had to make while reviewing the exhibits. First, because the documents were redacted, I assumed that the same California-based procurement business identified in the exhibits were procuring the human fetal tissue from and making payments to the California-based abortion clinics identified in Exhibits D1 through D3. My second assumption is that the same human fetal tissue procured in California was sent to research facilities in Massachusetts and Illinois, as indicated in exhibit C4. Third, I assumed that all the documents would be deemed admissible under the Federal Rules of Evidence. And fourth, I assumed that

the government's case would include testimony from cooperating or compelled employees or former employees of the various abortion clinics and/or human fetal tissues procurement companies – whom prosecutors commonly refer to as "storytellers" -- and possibly other evidence to support what the documents purport to inform.

a. The Abortion Clinics

The marketing materials that the procurement business provides to the abortion clinics explicitly states that financial profits will result from this partnership. (*See* Ex. B2 & B3). Additionally, the Middleman Turnkey Business Flow Chart (Ex. C1) indicates that procurement business pays the clinic "per tissue;" not a reasonable payment for any of the listed services in the statute. This "price per sample" business model is also supported by the payments to the various abortion clinics as set forth in exhibits D1 through D3. If a federal prosecutor can establish that these abortion clinics are not providing services for the "transportation, implantation, processing, preservation, quality control or storage of human fetal tissue," as these services are provided by the procurement business's embedded technicians, then these per tissue payments appear to be "valuable consideration" in violation of the statute. In fact, if the abortion clinic incurs no identifiable cost but is simply providing the procurement business with access to what would otherwise be discarded, then the "payments per tissue" are pure profits, in violation of both the letter and spirit of the legislation.

b. The Procurement Business

In my opinion, a deeper analysis of the procurement company's financials is necessary in order to establish the "valuable consideration" element beyond a reasonable doubt. An ethical federal prosecutor should not seek an indictment unless he or she can reasonably expect to prove all the elements of the offense beyond a reasonable doubt – not just establish probable cause in

order to obtain an indictment. Because the procurement business does in fact incur costs "associated with the transportation, implantation, processing, preservation, quality control or storage of human fetal tissue," a forensic account would be essential to breaking down the company's financials and the actual costs associated with the procurement business' acquisition, receipt, and transfer of the human fetal tissue it brokers. As a prosecutor, I would not want the success of my case hinging on a jury determination of which costs, for which tissues, are "reasonable" or not. Moreover, while the clinic growth strategy and revenue growth charts (Exs. B4 & B5) establish significant growth of the business, more is needed to determine whether the business is covering its increased costs or in fact profiting from its acquisition, receipt, and transfer of human fetal tissue.

Other Theories of Criminal Liability

a. Aiding and Abetting

Title 18, section 2(a) of the United States Code, states: "Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal." Generally, aiding and abetting does not need to be specifically alleged or cited. Instead, it is an alternative theory of culpability. If, however, the procurement business was charged as an aider and abettor, the prosecution would first need to establish that the crime was committed by the abortion clinic. Second, that the procurement business helped or encouraged the abortion clinic to commit the crime. And third, that the procurement business intended to help commit or encourage the crime.

Based on the limited exhibits provided, this aiding and abetting theory would, in my opinion, be a stronger theory of culpability for the procurement business. From the marketing materials provided by the procurement business to the abortion clinics, there is arguably proof

beyond a reasonable doubt that the procurement business "aided and abetted" the abortion clinics to profit from the interstate transfer of human fetal tissue.

b. Conspiracy

Title 18, section 371, of the United States Code states: "If two or more persons conspire either to commit any offense against the United States, . . . in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both." A conspiracy is an illegal agreement that a defendant knowingly joins. Additionally, a defendant must have performed or caused someone to perform one or more overt acts for the purpose of advancing or helping the conspiracy succeed.

Based on the limited exhibits reviewed and the strength of the substantive case against the abortion clinics, pursuing a conspiracy count against the procurement business, rather than a substantive count, may be a stronger theory of culpability as it relates to the procurement business.

Conclusion

In my opinion, and assuming the validity and admissibility of the exhibits provided to me, there is sufficient evidence to launch a federal grand jury investigation targeting the abortion clinics and the procurement business identified in the exhibits for potential violations of 42 U.S.C. § 289g-2, aiding and abetting violations of the statute, and conspiracy to violate the same. As for the substantive offense, proof that the abortion clinics received valuable consideration for their role in the transfer of human fetal tissue is, in my opinion, strong. As to the procurement business, further investigation is necessary to establish this element beyond a reasonable doubt.

Based on my experience, federal prosecutors take pride in protecting the most vulnerable among us. The federal prosecutors I proudly served with at the U.S. Attorney's Office in the Western District of Michigan and in the Eastern District of Virginia did not shy away from the tough cases, and they put their personal politics aside when asked to evaluate cases for prosecution. Evidence, or the lack thereof, not politics, should determine whether a U.S. attorney empanels a grand jury to investigate abortion clinics and human fetal procurement businesses in their districts.

Again, I thank you Chairman Blackburn, Ranking Member Schakowsky, and Distinguished Members of the Select Investigative Panel for allowing me this opportunity to provide my perspective on this issue. I welcome your questions.

Mrs. BLACKBURN. Thank you, Mr. Lennon.
Mr. Norton, you are recognized for 5 minutes.

STATEMENT OF MICHAEL J. NORTON

Mr. NORTON. Thank you, Madam Chair and Ranking Member Schakowsky, and esteemed members of the committee. My name is Michael J. Norton. I am an attorney in the private practice of law in Denver, Colorado.

I have had the privilege of serving as United States Attorney for the State and district of Colorado. I was first appointed by President Ronald Reagan and then reappointed by first President Bush.

Ms. DeGette, nice to see you again.

I have a written statement, which I respectfully request be incorporated into the record. I simply just want to summarize my comments and my remarks in the time that is available.

First of all, I will say to the committee that this is not about women's health. It is not about abortion, how one stands on the issue of abortion. It is whether or not there is probable cause to believe that crimes have been committed and, if so, what to do about that. To do nothing about the potential of the commission of criminal crimes is indeed flouting the criminal justice system of this Nation, and I think preferring those who are in well-connected places over those who are not.

So I suggest to you at the outset, Madam Chair and members of this committee, that what this committee is about is highly important and very critical to the criminal justice system and to the sanctity of that system in the United States of America.

It is really not about the issue of abortion, because potential profiteering and trafficking in aborted fetal tissue is of grave concern, not only on a Federal level but also in many States, including my own State of Colorado, which has adopted a law similar to the Federal law that is being looked at by this committee today.

There are many, many people, therefore, concerned that not only this Federal statute, but also the State statutes at issue, have been violated and are being flouted by the abortion industry. In 2015, it was revealed by one of these undercover videos that Denver's Planned Parenthood of the Rocky Mountains was indeed making a profit by harvesting and trafficking the hearts, the brains, the lungs, the eyes, the livers, and other body parts of babies whose lives Planned Parenthood had ended by abortion.

These gruesome revelations came from a series of videos released by the Center for Medical Progress that the committee has talked about. And it was clear from the videos that Planned Parenthood had been actively engaged in harvesting and trafficking for profit body parts of babies whose lives Planned Parenthood had ended.

Those videos have not created a general queasiness about surgery and blood. No matter how one stands on the issue of abortion, no one who has viewed these videos can come away thinking that Planned Parenthood's harvesting and selling of these baby body parts is consistent with our values or consistent with the law.

If wrongdoing has occurred, and I concur with the assessment Mr. Lennon has made of the facts and the circumstances as to the commission of crimes in this case, and I would add that it appears to me, quite frankly, that criminal violations of the Health Insur-

ance Portability Act, HIPAA, have also been committed by the embedding of the procurement business technician in the abortion facility itself. And the review by that technician of privileged medical records of patients in order to determine which body parts that technician wants to have harvested and sold to him has also been committed.

There are some facts that need to be determined, and a competent criminal investigation could determine those facts. But to do nothing is simply wrong, Madam Chair and members of this committee, and I thank the committee for its courage in moving into this area, investigating this area. I urge it to complete its investigation and to refer this matter to the U.S. Department of Justice for appropriate action, which I pray and hope is taken.

Thank you, Madam Chair.

[The prepared testimony of Mr. Norton follows:]

TESTIMONY OF MICHAEL J. NORTON

Regarding the Investigation by the Select Committee on Infant Lives of the U.S. House of Representatives' Energy and Commerce Committee into Potential Violations of 42 U.S.C. 289g-2 Concerning Unlawful Transfers of Fetal Tissue

Chairman Blackburn, Ranking Member Schakowsky, and Esteemed Members of the Select Committee on Infant Lives:

My name is Michael J. Norton. I am an attorney with the Denver law firm of Thomas N. Scheffel & Associates, P.C. Over the years, I have tried over 200 cases and have appeared in numerous federal and state courts, including in Colorado, Florida, Iowa, Louisiana, Missouri, Texas, Pennsylvania, Washington, and Wyoming.

I am currently admitted to the United States Supreme Court, the United States Court of Appeals for the Tenth Circuit, the United States Court of Appeals for the Eighth Circuit, the United States Court of Appeals for the Fifth Circuit, the United States Court of Appeals for the Ninth Circuit, the United States District Court for the District of Colorado, the United States District Court for the Western District of Washington, the United States District Court for the Southern District of Texas, the United States District Court for the Southern District of Iowa, and the United States District Court for the District of Columbia. I am also a member of the bars of the State of Colorado and the Commonwealth of Virginia.

By way of background, I was appointed United States Attorney for the District and State of Colorado by President Ronald Reagan in 1988. I was reappointed to this office by President George H.W. Bush in 1990.

As Colorado's United States Attorney, I served as the chief federal law enforcement officer for the State of Colorado and directed the United States Department of Justice's criminal and civil justice priorities. During my service as United States Attorney, I headed numerous federal investigations and prosecutions of organized crime trafficking in narcotics and dangerous drugs, environmental crimes, financial institution crimes, and securities frauds. I also coordinated the Justice Department's massive criminal investigation and prosecution of Rockwell International Corporation for environmental crimes at the Rocky Flats Nuclear Weapons Plant in Golden, Colorado. The conviction of Rockwell International Corporation led to the imposition of a fine of $18.5 million – the largest criminal hazardous waste fine in U.S. history to that time.

Both before and after my service as United States Attorney, I have been engaged in the private practice of law. My law firm Thomas N. Scheffel & Associates focuses in, among other legal areas, estate planning and probate litigation, business law, complex civil litigation, and white collar criminal defense.

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Federal law prohibits the harvesting and trafficking of fetal body parts for profit, and provides for criminal penalties for those who knowingly ignore the law. 42 U.S.C. § 289g-2. The law, passed by a Democratic-controlled House and Senate and signed by President Clinton in 1993, has, as its central tenet, the principle that there will be no profit from the harvesting and use of fetal tissue.

Thus, this law expressly states that it is unlawful for any person to "knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."[1] 42 U.S.C. § 289g-2(a). It is further unlawful "for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and . . . the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration[2] for the costs associated with such abortion." 42 U.S.C. § 289g-2(b)(3).

Federal law also establishes substantial limitations on the use of fetal tissue for "research." 42 U.S.C. § 289g-1. The informed consent of the mother of the unborn child is required. 42 U.S.C. § 289g-1(b). The law also prohibits any "alteration of the timing, method, or procedures used to terminate the pregnancy ... solely for the purposes of obtaining the tissue." 42 U.S.C. § 289g-1(c)(4).

The potential profiteering and trafficking in aborted fetal tissue is of grave concern, not only on the federal level, but also in many states, including Colorado. A number of states, including Colorado, have adopted laws regarding trafficking in fetal tissue that are similar to the federal statute. Many are therefore concerned that these state statutes, as well as the federal statute, have been violated and are being flouted by the abortion industry.

In 2015, it was revealed that Denver's Planned Parenthood of the Rocky Mountains was making a profit by harvesting and trafficking the hearts, brains, lungs, eyes and livers of babies whose lives Planned Parenthood has ended by abortion. These gruesome revelations came from a series of videos released by an organization called the Center for Medical Progress[3] which demonstrated that various affiliates of Planned Parenthood Federation of America, including Denver's Planned Parenthood of the Rocky Mountains, had been actively engaged in harvesting and trafficking, for profit, body parts of babies whose lives Planned Parenthood has ended by abortion.

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[1] "Interstate commerce" has been construed extremely broad by the U.S. Department of Justice. See, e.g., Jonathan H. Adler, "How the Justice Department is using the Commerce Clause to criminalize forcible beard cutting as a hate crime," *The Washington Post*, June 24, 2014; available at https://www.washingtonpost.com/news/volokh-conspiracy/wp/2014/06/24/how-the-justice-department-is-using-the-commerce-clause-to-criminalize-forcible-beard-cutting-as-a-federal-hate-crime/.

[2] "Valuable consideration" does not, by definition, "include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue." 42 U.S.C. § 289g-2 (e)(3).

[3] These videos may be accessed at the Center for Medical Progress's website at http://www.centerformedicalprogress.org/cmp/investigative-footage/

In the first video released by the Center for Medical Progress, Planned Parenthood Federation of America executive Deborah Nucatola was shown in a Los Angeles restaurant discussing prices for the body parts of aborted babies. Ms. Nucatola was recorded as stating that Planned Parenthood's abortionists would alter abortion procedures in order to further Planned Parenthood's organ harvesting and trafficking program. One such way, she related, was by using an ultrasound where ordinarily it would not be used so as to prevent damage to valuable organs of aborted babies.

These videos have not simply created a generalized queasiness at surgery and blood. No matter how one stands on the issue of abortion, no one who has viewed these videos has come away thinking that Planned Parenthood's harvesting and selling of the lungs, hearts, brains, or other organs of unborn babies is consistent with the values of our American society. Moreover, this conduct may well have violated 42 U.S.C. § 289g-2 and, if so, there should be some accountability on the part of the wrongdoers.

The harvesting and trafficking, for profit, of body parts of babies whose lives have been ended by abortion is a grisly business and it needs transparency. That transparency, a clear trail with readily identifiable links tracking the organs and tissues taken from an aborted baby, through the harvesting process, through every transportation of each body part, and eventually to final use and disposal, is essential to show whether any statute has been broken.

In particular, the details of all payments, expenses, costs, and persons involved with any of the actions or monetary transfers is indispensable in deciding whether the statute has been violated.

Unfortunately, to date, no Executive Branch agency appears to have taken any responsibility to investigate potential violations of current federal law. Because we are a Nation of laws, this fact alone makes this investigation by the Select Committee on Infant Lives of the U.S. House of Representatives' Energy and Commerce Committee into potential violations of 42 U.S.C. § 289g-2 very important to our system of ordered liberty.

When I was asked to testify before the Select Committee on Infant Lives on this matter, I started where I would have started as U.S. Attorney in any criminal investigation – with the relevant statute and the elements of the criminal offense. I was supplied with and reviewed documents and evidence that the Select Committee on Infant Lives has gathered.

The relevant statute is quite clear – the central question is whether anyone has profited from the sale of hearts, brains, livers, and other organs harvested from aborted babies. It seems clear from the documents and evidence that the Select Committee on Infant Lives has gathered, as well as the videos I have reviewed, that there has been profiteering at multiple levels in this grisly business.

Congress is rightly alarmed by the evidence that has emerged to date that there has been profiteering from the sale of hearts, brains, livers, and other organs harvested from aborted babies. Our

Nation is rightly served by the aggressive pursuit of the truth by the Select Committee on Infant Lives. I commend the Select Committee on Infant Lives for its diligence.

In my opinion, there is probable cause to believe that the relevant statute has been violated. It is therefore also my opinion that our Nation would also be well-served by an aggressive investigation and, should the facts support it, the prosecution of these criminal violations by the appropriate federal authorities.

I therefore urge the Select Committee on Infant Lives to forward its evidence and findings to the U.S. Justice Department with the request that the U.S. Justice Department take all necessary and appropriate action available to hold those who have violated this law accountable.

I am honored to have been asked to participate in this hearing and will be pleased to assist the Select Committee on Infant Lives in whatever way I am able.

Thank you.

Mrs. BLACKBURN. Thank you, Mr. Norton.
Ms. Foster, you are recognized for 5 minutes.

STATEMENT OF CATHERINE GLENN FOSTER

Ms. FOSTER. Thank you. Ms. Chairman, Ms. Schakowsky, distinguished members of this Panel, I am privileged to present this testimony concerning the pricing of human fetal tissue. My views are consistent with those of the Charlotte Lozier Institute, where I am an associate scholar, which is dedicated to advancing science, medicine, and research in the service of human life and to promoting a culture and polity of life.

My views are similarly consistent with those of Sound Legal, a law firm and legal organization advocating for the universal right to life. As an attorney, I have dedicated my career to advocating for the right of every innocent human being to be protected. And so I am troubled by those in the abortion and tissue procurement industry who scheme to trade in baby body parts for their own financial enrichment.

The public learned of these back alley transactions last year when undercover videos of the organ business brokers surfaced online. Indeed, the trade in fetal body parts is a business. As demonstrated by the evidence presented by this Panel, clinics and procurement companies have been getting away with charging far more than the allowed costs for harvesting, transporting, and warehousing body parts as they wait for customers.

In doing so, they have violated both the intent and the letter of Section 289g-2, which bars, among other things, the transfer of human fetal tissue for valuable consideration. The statute's definition of "valuable consideration" is straightforward. If payment is not reasonable or not associated with the transplantation, implantation, processing, preservation, quality control, or storage of human fetal tissue, it is not permitted.

We can all agree on this statute. It passed with bipartisan support in a Democratic Congress and was signed into law by President Clinton. Representative Waxman at the time called the fetal corpse market "abhorrent," and yet the Panel's evidence reveals that abortion clinics are being promised a profit, and are paid, even when they have no apparent costs to be reimbursed, and further multiplying a clinic's windfall via savings on disposal services.

Tissue procurement companies are likewise paid exorbitantly by their customers. This market in baby organs and tissues demonstrates a flagrant and repeated disregard for the rule of law. It was no surprise when America's biggest abortion business, facing public and prosecutorial exposure, relented and agreed to end its longstanding practice of receiving direct payments for baby body parts.

And yet, in my years of work in this field and in the 23 years that Section 289g-2 has been law, I am unaware of a single instance in which it has been enforced. This Panel is right to shine a light on Big Abortion's back alleys.

For perhaps we forget that this law was meant to protect the ethical imperative that recognizes the dignity in every human life. In the face of clinical, sanitized language, we may become desensitized. In the abortion clinic, a human baby is called "tissue" or

a "fetus." A head is a "calvarium" or "cal." The technician who counts body parts is a products of conception, or POC, worker.

And by converting human lives into a bulk commodity, public discussion has been stifled. But we are in fact talking about real and unique human beings whose lives were tragically snuffed out. We are talking about affording them the minimal dignity that comes with not having their remains further picked through to be bought and sold like chattel.

I know that the abortion industry and its allies are waging a campaign against any effort at transparency or accountability. It is what we can expect from a big business with an emphasis on maximizing profits and a lot of money to lose. And so Big Abortion is fighting back with all its financial and political might, investing its political and monetary stockpile to buy public sanction, and weighing its thumb down on the scales of justice with high-profile PR firms, pocket politicians, and spellbound media.

With these allies, until now, the abortion industry has succeeded in shouting down the voices acknowledging the public evidence of guilt and crying out for justice. But no more. We, the people, are not afraid of confronting the truth, and we encourage this Panel and those in law enforcement to pursue it. Common sense and common decency demand enforcement of Section 289g-2.

Thank you.

[The prepared testimony of Ms. Foster follows:]

Testimony of Catherine Glenn Foster
Associate Scholar, Charlotte Lozier Institute
CEO and General Counsel, Sound Legal
Hearing on the Pricing of Fetal Tissue
Select Investigative Panel on Infant Lives
U.S. House of Representatives
April 20, 2016

Hon. Marsha Blackburn, Chair
Hon. Janice Schakowsky, Ranking Member
Honorable Members
United States House of Representatives
Committee on Energy and Commerce
Select Investigative Panel
2125 Rayburn House Office Building
Washington DC 20515

Ms. Chairman, Ms. Schakowsky, and Members of the Panel:

I am privileged to present this testimony concerning the pricing of human fetal tissue. My views are consistent with those of the Charlotte Lozier Institute, where I am an Associate Scholar, and which is dedicated to advancing science, medicine, and research in the service of human life and to promoting a culture and polity of life. My views are similarly consistent with those of Sound Legal, a law firm and legal organization advocating for the universal right to life.

As an attorney, I have dedicated my career to advocating for the right of every innocent human being to be protected. And so I am troubled by those in the abortion and tissue procurement industry who scheme to trade in baby body parts for their own financial enrichment. The public learned of these back-alley transactions last year when

undercover videos of the organ business brokers surfaced online. Indeed, the trade in fetal body parts is a business. As demonstrated by the evidence presented by this Panel, clinics and procurement companies have been getting away with charging far more than the allowed costs for harvesting, transporting, and warehousing body parts as they wait for customers. In doing so, they have violated both the intent and the letter of 42 U.S.C. § 289g-2, which bars, among other things, the transfer of human fetal tissue "for valuable consideration."

The statute's definition of "valuable consideration" is straightforward: if a payment is not reasonable or not "associated with the transplantation, implantation, processing, preservation, quality control, or storage of human fetal tissue," 42 U.S.C. § 289g-2(e)(3), it is not permitted. We can all agree on this statute; it passed with bipartisan support in a Democratic Congress and was signed into law by President Clinton. Rep. Waxman called the fetal corpse market "abhorrent."

And yet, the Panel's evidence reveals that abortion clinics are being promised a profit and are paid even when they have no apparent costs to be reimbursed, which further multiplies a clinic's windfall via savings on disposal services. Tissue procurement companies are likewise paid exorbitantly by their customers. This market in baby organs and tissues demonstrates a flagrant and repeated disregard for the rule of law. It was no surprise when America's biggest abortion business, facing public and prosecutorial exposure, relented and agreed to end its longstanding practice of receiving direct payments for baby body parts.

And yet, in my years of work in this field, and in the 23 years § 289g-2 has been law, I am unaware of a single instance in which it has been enforced. This Panel is right to shine a light on big abortion's back alleys.

For perhaps we forget that this law is meant to protect the ethical imperative that recognizes the dignity in every human life. In the face of clinical, sanitized language, we may become desensitized. In the abortion clinic, a human baby is called "tissue" or a "fetus." A head is a "calvarium" or "cal." The technician who counts baby body parts is a "products of conception" or "POC" worker. And by converting human lives into a bulk commodity, public discussion has been stifled. But we are in fact talking about real and unique human beings whose lives were tragically snuffed out. We are talking about affording them the minimal dignity that comes with not having their remains further picked through to be bought and sold like chattel.

I know that the abortion industry and its allies are waging a campaign against any effort at transparency or accountability. It is what we can expect from a big business with an emphasis on maximizing profits and a lot of money to lose. And so big abortion is fighting back with all its might, investing its political and monetary stockpile to buy public sanction, and weighing its thumb down on the scales of justice with high-profile PR firms, pocket politicians, and spellbound media. With these allies, until now, the abortion industry has succeeded in shouting down the voices acknowledging the public evidence of guilt and crying out for justice. But no more. We the people are not afraid of

confronting the dirty truth, and we encourage this Panel and those in law enforcement to pursue it. Common sense and common decency demand enforcement of § 289g-2.

Mrs. BLACKBURN. Thank you, Ms. Foster.
Mr. Sukhia, you are recognized for 5 minutes.

STATEMENT OF KENNETH W. SUKHIA

Mr. SUKHIA. Thank you, Madam Chairman, and the members of this committee. I was privileged and honored to serve as the United States Attorney for the Northern District of Florida, and before that was an Assistant U.S. Attorney for 10 years.

Much of my expertise that I could lend to the committee would be in, of course, the area of determining whether a grand jury should be empaneled, whether a case should proceed, whether investigation should be pursued. And I have heard it said today that this is a committee that has disdain for the truth, that this is not a fact-based inquiry, and when I look at the exhibits that were submitted, but also, of course, when I looked at the videos that were presented, it strikes me as odd that there would not be an aggressive and meaningful investigation into the allegation that indeed human baby parts are being sold for profit.

Article II, Section 3, of our United States Constitution, in fact, requires of the executive branch that it faithfully execute the laws of the country. By not faithfully executing those laws, you are in fact taking specific affirmative action to defy what is required by the Constitution.

And in this situation, it is beyond my assessment and belief that when you have a procurement industry that is actually marketing to the abortion clinics that they can procure or work to gain more profits by this method and when they are seeding their own employees in the clinic to do those jobs that would indeed cost and would indeed be the services that would compromise the legitimate cost or payment for those services, then the question clearly arises: Have these clinics profited from this process? It is a very si,mple, basic issue.

And so we are not saying as a prosecutor when someone comes in the door with this evidence, "Oh, this is absolutely, positively a fact." We are saying, "No, this justifies a full and complete and a thorough investigation." And I think there does seem to be a pattern when, "Oh, this can't possibly have any basis because, let's see, 16 years ago someone lied. So we can't take this. This is the same sort of thing that has happened before."

And we should also stop the prosecution of all murders because there have been cases where persons have lied and people have been wrongly convicted. And the whole argument is nonsense and, in fact, this whole notion that, "Oh, let's fall all over ourselves," to insist that, "Oh, we are being—this is nothing but an effort to attack the reproductive rights of our citizens," when it is in fact an effort to enforce the law, which is required of our Constitution.

Thank you.

[The prepared testimony of Mr. Sukhia follows:]

TESTIMONY OF KENNETH W. SUKHIA
BEFORE THE COMMITTEE ON ENERGY AND COMMERCE
SELECT PANEL ON INFANT LIVES
INVESTIGATIVE PANEL
ON "THE PRICING OF FETAL TISSUE"

APRIL 20, 2016

Madam Chairman Blackburn and Members of the Select Investigative Panel. I am pleased to address the Committee today on the subject of the Panel's inquiry, "The Pricing of Fetal Tissue."

I am a former United States Attorney appointed by the first President Bush who served 13 years as a federal prosecutor and who clerked for a Florida Supreme Court Justice and a Judge on the U. S. Court of Appeals for the Eleventh Circuit in Atlanta. I have been a private practitioner for 23 years and during that time I have handle numerous high profile cases, including the federal military and absentee ballot cases representing George W. Bush in the 2000 recount battle and the defense of Florida's Lobbyist Disclosure Act representing the President of the Florida Senate.

At Governor Bush's request, I also represented the State of Florida in a hard fought eight-day trial against Planned Parenthood when it challenged to the Constitutionality of Florida's Parental Notice of Abortion Act. Through that trial I gained unique insight into the workings not only Planned Parenthood, but the abortion industry as a whole. Based on the evidence we presented from clinic operators, former abortion physicians and abortion clinic owners, I can assure this Panel that maximizing profit is a major priority of the abortion industry. The importance of profit to the industry is underscored by testimony in our case that the average time the typical abortion doctor

spends with each patient is approximately 10 minutes. Abortion providers testified it is not uncommon for abortion clinic physicians to perform four or more abortions per hour and one provider indicated that in 20 years he had personally had performed over 100,000 abortions. Depending on the stage of fetal development our evidence showed the typical clinic abortion procedure cost abortions cost between one to three thousand dollars. As the appeals court noted in our case, evidence at trial showed that "the physician-patient relationship is often attenuated in the abortion context, almost to the point of non-existence." *North Florida Women's Health and Counseling Services v. State*, 852 So.2d 254, 264 n.3 (Fla. 1st DCA 2003) *rv'd on other grounds,* 866 So.2d 612 (Fla. 2003) ("Abortion patients ordinarily see their physicians only once or twice, very briefly. Most of their interaction is with the clinic's staff. Physicians performing abortions often perform several in the space of a single hour."). Based on my many months in discovery and my experience in trial, I was not surprised by the profiteering interests of the abortion clinic executives displayed by in the videos released last summer.

However one feels about the sanctity of life, most would agree that trafficking in infant body parts for profit is an abhorrent practice that should never be tolerated in America. Congress made it a crime to do so. Title 42 USC §289 g-2. The release of the Planned Parenthood and abortion clinic videos last summer offered another glimpse into abortion industry's own dark alleys. Ironically, while state authorities have been aggressively pursuing the investigation and prosecution of those who are alleged to have violated the less serious offense of non-consensually recording videos, federal authorities have been reluctant to investigate the activities and enforce the criminal laws against those whose conduct appears to violate the far more egregious federal offense of profiting

from the harvesting and transferring of unborn human body parts. Accounting and marketing materials from the fetal tissue procurement business demonstrate beyond question that there is more than sufficient cause to support a full investigation by federal authorities to determine if such practices violate the felony provisions of 42 USC §289 g-2. Unfortunately, much like its selective approach to the enforcement of other federal offenses, the Administration has failed to investigate potential violations and enforce our criminal laws in this area.

Civilized societies are distinguished by the protections they afford their weakest and most vulnerable members, and our government acts its noblest when it speaks for those who have no voice. To decry an effort to investigate and enforce our criminal laws forbidding the transfer of fetal body parts for profit in the face of the documents set out in this record is to shirk the government's rightful duty to enforce the Congressional mandate forbidding such practices, and to ignore the government's important responsibility to prevent what the statute's sponsors recognized as an abhorrent practice. To create a market for the sale of unborn human body parts is also to promote an ethic that belies the government's primary purpose of protecting and preserving the lives of its citizens. Our forefathers, who pledged their *own* lives to form the government under which we live, knew this purpose well, and perhaps better than we do today. "The chief aim of government," they said, "is to protect life; abandon that and you have abandoned all."

Mrs. BLACKBURN. Thank you, Mr. Sukhia.

At this time, we will begin the——

Mr. NADLER. Madam Chair?

Mrs. BLACKBURN [continuing]. Questioning on our——

Mr. NADLER. Madam Chair?

Mrs. BLACKBURN [continuing]. Side. Yes, the gentleman is recognized.

Mr. NADLER. Parliamentary inquiry, please.

Mrs. BLACKBURN. Parliamentary inquiry. State your inquiry.

Mr. NADLER. Yes. Madam Chair, the witnesses appear to have relied heavily on the premise from your staff that clinics incur no costs related to fetal tissue donation. That premise is captured in Exhibit G, which you previously had up on the screen. Could you put that up on the screen for a moment again, please, while I complete the parliamentary inquiry? Exhibit G.

Mrs. BLACKBURN. Let's bring up Exhibit G, and please state the inquiry.

Mr. NADLER. Is that Exhibit G? That is not Exhibit G. That is it. Thank you.

Madam Chair, this chart says that the clinic has "no costs so the payments ... are pure profit" for the clinic." This is contradicted by Exhibits C6, C9, and C17, which show that some clinics obtain consent, draw blood, fill out paperwork, among other things, related to fetal tissue donation. These are all requests that the Government Accountability Office recognized 16 years ago as reimbursable "direct costs."

Madam Chair, can you explain how this document, Exhibit G, was created and its factual foundation, including the discrepancy between what this staff-created chart asserts, namely that there are no costs, and information on other documents in your packet, Exhibits C6, C9, and C17, which detail such costs?

Mrs. BLACKBURN. I thank the gentleman for the inquiry. We discussed this previously before you arrived at the hearing, and all of the documents today come from the investigative work that took place by submissions that came to us, whistleblower information. The charts for discussion, of which G is one, were compiled from that work by our staff, and at this time we begin our questioning——

Mr. NADLER. Madam Chair, further parliamentary——

Mrs. BLACKBURN [continuing]. And I turn to Mr. Pitts.

Mr. NADLER [continuing]. Further parliamentary inquiry, and I don't believe——

Mrs. BLACKBURN. State the inquiry.

Mr. NADLER. Thank you. I don't believe this was discussed while I was at the Judiciary Committee: How can you explain the discrepancy between the information on Exhibit G, namely that no costs were incurred, and the information on Exhibits C6, C9, and C17, which lists some of those costs? That didn't happen.

Mrs. BLACKBURN. There is no discrepancy, and I thank the gentleman for the inquiry. At this time, we begin——

Mr. NADLER. I will show you the discrepancy——

Mrs. BLACKBURN [continuing]. We begin our hearing with Mr. Pitts.

Mr. NADLER. Further parliamentary—of course there is a discrepancy.

Mrs. BLACKBURN. Do you have a motion?

Mr. NADLER. No. I have a parliamentary inquiry, and I will——

Mrs. BLACKBURN. OK.

Mr. NADLER [continuing]. Which is being sidestepped and not answered. This Exhibit G says, "Abortion Clinic: Explanation: The" abortion clinic "has no costs so the payments from the PB," the procurement business, "to the AC," the abortion clinic, "are pure profit. All costs are borne by the PB or the Customer."

Exhibit C9 says—it is an exhibit of clinic procedures and policies, and it says, "you must inform": "you"—the employee—"must inform the Assistant Manager and HSS's when you have completed your work. This will insure they do not continue to consent and draw unnecessary blood samples." The interaction of——

Mrs. BLACKBURN. If the gentleman will yield, you are citing a procurement business procedure. So one is the clinic, one is the procurement business. I thank the gentleman for the inquiry.

Mr. NADLER. The procurement business has to tell the clinic staff, which has to be satisfied, and that takes time and there is a direct cost.

Mrs. BLACKBURN. At this——

Mr. NADLER. So they have to tell the abortion clinic that they are done, so that the abortion clinic does not continue to take more samples, et cetera, which is a direct cost for the clinic, not the procurement business. So that is a direct contradiction of——

Mrs. BLACKBURN. The documents are separate. It is not a direct contradiction, and the documents are separate. One relates to abortion clinic, the other to the permit business.

Mr. NADLER. If this is not a direct contradiction, what is the methodology to determine that there are no costs for the abortion clinic as asserted in Exhibit G, which apparently has no basis?

Mrs. BLACKBURN. It is all based on the investigatory work, and I thank you for the parliamentary inquiry.

Mr. NADLER. Well——

Mrs. BLACKBURN. At this time, we are going to Mr. Pitts.

Mr. NADLER [continuing]. Investigatory—and further parliamentary——

Mrs. BLACKBURN. We have——

Mr. NADLER [continuing]. Further and final, I hope, parliamentary inquiry: Can you explain how using a chart that draws conclusions that have no objective basis in fact, other than your statement that somebody investigated, does not violate House rules prohibiting conduct that does not reflect creditably, or may discredit or dishonor the House and this Panel, Rule 11, Clause 4, and Rule 23, Clause 1? Because what I am hearing is that staff people somehow derived this information. We are not told how, what——

Mrs. BLACKBURN. Mr. Nadler, you know, this is not a parliamentary inquiry.

Mr. NADLER. Oh, yes, it is.

Mrs. BLACKBURN. Basically, you are trying to debate the documents, and we need to move on with our questions.

Mr. NADLER. How is this not——

Mrs. BLACKBURN. And I am turning to Mr. Pitts. Mr. Pitts, you are recognized for 5 minutes for questions.

Mr. PITTS. Thank you, Madam Chair, for calling this important hearing on the pricing of fetal tissue. This issue has caused me considerable concern because one of the underpinnings and safeguards of the statute that allowed for the donation of fetal tissue for transplantation and research was that this tissue would not be sold.

The author of the statute, Representative Waxman, stated during the floor debate in 1993, and I quote, "It would be abhorrent to allow for the sale of fetal tissue and a market to be created for that sale." And yet this is what is happening, as one of the witnesses said, in the back alleys today.

As seen on Exhibit B2 and B3, the procurement business markets itself on its brochure as a way for clinics to make additional income by allowing the procurement business, procurement technicians, to take fetal tissues and organs from aborted babies immediately after the abortion was completed using the words "financially profitable," "fiscally rewards," "financial benefit" on its brochure.

The Select Panel investigation reveals that every conceivable harvesting task is performed by the technician employed by the procurement business. And so procurement businesses, essentially the middleman, are paying fees to abortion clinics, but the abortion clinics are incurring no costs. Exhibit D shows payments from the procurement business to abortion clinics for aborted babies and baby blood.

Exhibit D1. The abortion clinic charged the middleman with a bill for $11,365 in August of 2010 for baby parts and blood that the middleman's technicians harvested. Another invoice in January/February of 2011 charged $9,060 for harvested baby parts and blood. The middleman even makes it easy for the researcher to purchase baby body parts. Exhibit C3, the procurement business order form, or the dropdown menu for baby organs, shows just how easy this is.

First, it asks on the left side, "What type of tissue would you like to order?" And I suppose you could respond, anyone could respond to this, "I would like to order brains." And then it says, "Number of Specimens." Well, six, let's say, baby brains. "Gestational Range Start" and "End." Well, that would be 16 to 18 weeks.

And then here is another question: "Add another tissue type?" You could say "yes." Another tissue type listed, ″Female Reproductive System and Ovaries." You could say, "I take five of those at 15 weeks." You could add, you know, five baby tongues.

"Shipping Options." You could respond, "Yes, I want it rush ordered." So, for crying out loud, this is the Amazon.com of baby body parts. There is a market for baby body parts, and you get what you pay for. This is absolutely repulsive. And we must not forget, as was testified here, each one of these, you know, little baby brains or tongues represent a baby. How can anyone defend this practice?

All this shows, that in both intent and in practice, these organizations were making money well above the actual cost. So going back to Exhibit B2 and B3, the company brochure, the Web site, show intent, their publicity, marketing materials.

My question for the former prosecutors for DOJ—we will start with Mr. Sukhia, Mr. Norton—what communications or information would you seek to learn whether the intent of the procurement business and the abortion clinic was to profit from selling baby body parts? Mr. Sukhia, let's start with you.

Mr. SUKHIA. Yes, Congressman Pitts.

Mr. PITTS. Put on your mike.

Mr. SUKHIA. Yes, sir. I had pressed the button, and then it went off. Well, some of that evidence is already in this record. I have heard, again, everyone quickly rushing to insist that these videotapes are just deceptively prepared. In other words, do what we are extremely deft at doing, this industry, which is deflecting, and everyone else is at fault.

"Let's shift the focus so everyone is focused on, hey, what this—these videos did and what this person said in the—how he prepared the videos." But those videos were posted; all of those videos were posted. And there are some things that, when people say them on tape, it doesn't matter what they didn't say or did say elsewhere.

If someone is saying, "That would be good," and we are talking about profiting from this, and they are talking about that, that is corroborative evidence. It corroborates the evidence that you were identifying, Mr. Congressman, which is very strong evidence when someone is actually marketing for it. So I would——

Mrs. BLACKBURN. Let's answer quickly. Time has expired.

Mr. SUKHIA. I would also want to know what communications occurred between—other communications, email and so forth—back and forth between those people. We would seek those items as well, and of course the accounting records.

Thank you.

Mr. PITTS. I yield back. Thank you.

Mrs. BLACKBURN. The gentleman yields back.

Ms. Schakowsky is recognized for 5 minutes.

Ms. SCHAKOWSKY. Unfortunately, the majority has refused to even bring in the one party that actually could answer these questions, and that is StemExpress.

And I want to say, Mr. Sukhia and Mr. Norton, as lawyers, the fact that you keep referring back to these completely discredited videos by 3 Congressional panels, by the 12 States that looked into this, by a grand jury that ended up—you talk about the Center for Medical Progress, Mr. Sukhia, Sukhea, which is it? Sukhia?

Mr. SUKHIA. Sukhia. Thank you.

Ms. SCHAKOWSKY. Oh, sorry. And yet Mr. Daleiden and his partner were actually indicted as a consequence. So, you know, that is a comment. It is not a question. It is a fact that that has been looked into.

The other thing is, I want to ask Ms. Clayton a question, but I also want to go back to a letter and numbers of documents presented by StemExpress that would completely discredit the exhibits that have been mentioned. And I want to just—as far as B2, the majority's use of this brochure is misleading at best. It was used by StemExpress with hospitals and clinics involved in a broad spectrum of work that the company supports related to adult blood, adult tissue, biopsies, et cetera, not fetal tissue donation.

Exhibit B3, the StemExpress Web site screenshot, makes absolutely no reference to fetal tissue. In fact, it pertains to the overwhelming majority of StemExpress' work with adult blood and tissue that has nothing to do with fetal tissue, which accounted for less than 1 percent of the company's revenue in 2014 before losses.

They have repeatedly offered to come in and provide exactly the specific information that is raised in these exhibits, and that has been turned down. I think it is shameful for an investigation that seeks to get supposedly to the truth.

Now, I want to ask Ms. Clayton a question, and I think that this parallel is worth examining because the facts are the same: discredited video, which led to an investigation that found no guilt.

So I want to skip part of this but ask, there were accusations made against your client that impacted him, the client that was found to have done nothing wrong. And I wonder how it affected his business reputation, his own safety, and that of his family.

Ms. CLAYTON. Yes, Congresswoman Schakowsky. It was a company, Anatomical Gift Foundation, and it was threatened by terrorists on the anti-choice side, including the Army of God. That is the group that shot Dr. Tiller, not the time he was murdered but the time he was shot before his murder. Army of God is one of the most violent, outrageous, anti-choice groups around, and AGF, my client, received threats of that as soon as these outrageously fallacious videotapes were sent to Congress and got circulated, when they were on "20/20," and everybody believed they were true. "Oh, it must be true. We saw it on a videotape," not under oath.

I would just comment that anyone who wants to look at a defense of any of this, first thing you do, get Mr. Daleiden under oath, see what he says when the penalty of perjury would attach, because when Mr. Alberty was under oath in the deposition that I took, he suddenly started telling the truth, and what he told was that everything else was a lie.

Meanwhile, these threats endanger the life and safety of people at clinics all over the country, as in Colorado. A crazy Mr. Dear murdered three people because he thought it was true about these tapes, the sale of baby body parts, even though 12 States, the Texas grand jury have found that is completely fallacious.

Ms. SCHAKOWSKY. I just want to say, your client provided a letter sent by this anti-abortion group to your client's wife. In that letter, the group referenced "baby parts"—that is a quote—and warned her that it was "watching you and your husband" and that "this is only the beginning." And I seek unanimous consent to enter this March 9, 2000, letter.

Mrs. BLACKBURN. So ordered.

[The information appears at the conclusion of the hearing.]

Ms. SCHAKOWSKY. And I believe that there is a connection between the murders at the clinic in Colorado Springs following these deceptive videos where the murderer said, "No more baby body parts," and the repeat of that language and the repeat of the false accusations, and the collection of names—a database of names of people involved in research and in clinics—is dangerous. It is dangerous. We should not be doing that in the United States of America, and I yield back.

Mrs. BLACKBURN. The gentlelady's time has expired.

I yield to Ms. Black for 5 minutes.

Ms. BLACK. Thank you, Madam Chair, and I thank the panel for being here today. I do want to focus on Exhibit G, on who bears the responsibility for the tissue procurement chart. As a nurse, I am well aware of how important it is to follow procedures, especially in performing your duties when you are caring for a patient that has trusted you as a care provider for their medical treatment.

So let's walk through a day in the life of a procurement tech. And if you will please turn to Exhibit C for this question. In Exhibit C4, you will see that the tech gets an email like the one that is on C4, and she reads the order for certain baby body parts, including the gestation period, and knows what she needs to harvest for that day. And I want to reference the second from the bottom line, it says that she will need a brain, 16 to 18 weeks, and "Complete but can be in pieces." So she has a very specific tissue that she is looking for.

Now, if we can turn to C9, Exhibit C9, and then she informs the abortion clinic staff of what she will be procuring on that day. And we actually see there on the first line where she communicates with the assistant manager, says, "Upon arrival, inform the staff clearly of what you are procuring for the day."

So let's follow on, then, with Exhibit C5. The procurement tech then reviews the medical files—which is another subject, of whether this is a HIPAA violation, whether she has the right to be looking at those files of the patients to learn their names and the gestation time of their baby—and she records this in a gestation tracking log, essentially matching the patient with her needs, not the patient's needs but with her needs of what she has been given as her job for the day.

Let's next turn to Exhibit Number 8. Next, the procurement tech approaches the patient waiting for this abortion—and many times this is a young woman who is afraid, not always certain about what she is doing, and needs advice and counseling, but that is not what we see her getting here. This tech doesn't have much time, and she must match her orders with the patients who are at the right gestation time.

So she asks for the patient by name, and then she consents with them to donate by saying that her baby tissue is about curing for potential diseases, such as diabetes, Parkinson's, and heart disease.

And I want to also reference the second paragraph here where she actually says that "The law in the State of California," which is where this is being done, "requires that the tissue from your procedure be incinerated." If you go and look at the law there, she is leaving one thing out. She could offer to this mother to actually bury this baby, but that is left out.

She is given, I think, decisions that are very difficult: either you are going to incinerate this baby, or you are going to give this baby up for research. I think that you certainly should be counseling and giving all options to this young woman, who is in a very difficult situation in making that decision.

Now let's turn to Exhibit C12 and then after that C13, because, after the abortion the procurement tech collects the tissues and procures the baby body parts needed. She carries all of her supplies with her, and you will see here in this particular exhibit that she

has very detailed instructions about what she is putting these body parts into. So this is not coming from the abortion clinic. This is actually coming from the procurement agency that she is working for.

And then the tissue tech then arranges for the delivery. We can see that that is by FedEx. It is clear on the first exhibit and also on this one about who is paying for the delivery of this, not only the test tubes, and so on, that she will be using to put the specimen in.

So let's go back again to Exhibit G, where we see here in Exhibit G a blank on where the expenses are for the abortion clinic because, as I walked you through her day, there is nothing to indicate that the abortion clinic has incurred any expenses.

So let me ask you, Mr. Lennon, if you were to walk through this, how does this comprehensiveness of the tissue tech's work inform your thinking about whether the abortion clinic is profiting from the sale of baby body parts?

Mr. LENNON. Thank you. I did consider that in my analysis here, and so the question that was raised earlier in the parliamentary question by the representative from New York was that maybe there is a conversation, and in this case there was a conversation. But then the payment should be maybe for that conversation in the processing, because that is the only thing I see where the abortion clinic would have any cost incurred: for that conversation, not a price-per-tissue payment. That informs me that we are talking about the sale of a part, and not some reasonable cost.

The other, I think, attack that a defense counsel—which I now do—would say is, "Well, they are also involved in the processing because, you know, the client, the patient, is there," but the abortion itself is not the processing of the tissue. It is the creation of the tissue through the destruction of a human life.

So I think there is really no argument I saw from any of this that the abortion clinic had any other costs. They are getting a per-tissue payment.

Ms. BLACK. Thank you, Mr. Lennon. I yield back.

Mrs. BLACKBURN. The gentlelady's time has expired.

Ms. DeGette, you are recognized for 5 minutes.

Ms. DEGETTE. Thank you so much, Madam Chair. As a former litigator myself, there is nothing I like better than a panel of lawyers. I have a series of questions that I would prefer a yes-or-no answer, if I may.

The first question I have for the panel is, we received a packet of documents from the majority. I believe I have seen you all referring to it during this hearing in a binder. So my first question is, Have you seen these documents before today's hearing? Ms. Clayton, "yes" or "no"?

Ms. CLAYTON. Yes.

Ms. DEGETTE. Mr. Raben?

Mr. RABEN. Yes.

Mr. LENNON. Yes.

Mr. NORTON. Yes.

Ms. FOSTER. Yes.

Mr. SUKHIA. Yes.

Ms. DEGETTE. Thank you. And did you personally author any of these documents? Ms. Clayton?
Ms. CLAYTON. No.
Mr. RABEN. No.
Mr. LENNON. No
Mr. NORTON. No.
Ms. FOSTER. No.
Mr. SUKHIA. No.
Ms. DEGETTE. Have you spoken with anyone who authored any of the documents about the information that the documents contain?
Ms. CLAYTON. Not to my knowledge.
Mr. RABEN. No.
Mr. LENNON. Not to my knowledge.
Mr. NORTON. Not to my knowledge.
Ms. FOSTER. Not to my knowledge.
Mr. SUKHIA. Maybe. But I don't know.
Ms. DEGETTE. Who have you spoken with, then?
Mr. SUKHIA. Just the folks who contacted——
Ms. DEGETTE. Do you have names?
Mr. SUKHIA. Of the folks—March Bell, and I think that might be it.
Ms. DEGETTE. And that is from majority staff?
Mr. SUKHIA. Yes.
Ms. DEGETTE. Thank you. Now, for the documents that are listed in the index that accompanied the packet as coming from a "procurement business," have you spoken with that procurement business about the documents? Ms. Clayton?
Ms. CLAYTON. No.
Ms. DEGETTE. Mr. Raben?
Mr. RABEN. No.
Mr. LENNON. No.
Mr. NORTON. No.
Ms. FOSTER. No.
Mr. SUKHIA. No. No, and that is why there needs to be——
Ms. DEGETTE. Now——
Mr. SUKHIA [continuing]. An investigation.
Ms. DEGETTE. Excuse me. Now, do you have any firsthand knowledge of how the procurement business in question created the documents used in today's exhibits? Ms. Clayton?
Ms. CLAYTON. Absolutely not.
Ms. FOSTER. No.
Mr. LENNON. No.
Mr. NORTON. No.
Ms. FOSTER. No.
Mr. SUKHIA. No.
Ms. DEGETTE. And for the documents that are listed as staff-created, for example, Exhibits B4 and B5, did the Republican staff discuss those documents with you? Ms. Clayton?
Ms. CLAYTON. No.
Ms. FOSTER. No.
Mr. LENNON. Could you remind me what exhibits you are talking about?

Ms. DEGETTE. Well, the exhibits like the charts that were clearly staff-created.

Mr. LENNON. No.

Mr. NORTON. No.

Ms. FOSTER. No.

Mr. SUKHIA. I think—I think we did discuss that.

Ms. DEGETTE. You did discuss that with——

Mr. SUKHIA. I think the staff member indicated that those are——

Ms. DEGETTE. Did they tell you the documents, sir, that formed the foundation of those?

Mr. SUKHIA. No. The nature of——

Ms. DEGETTE. Thank you very much.

Mr. SUKHIA [continuing]. Their—well, the——

Ms. DEGETTE. My last question: Do you have any firsthand knowledge of what documents and facts the majority staff relied upon in the staff-created documents? Ms. Clayton?

Ms. CLAYTON. Absolutely no idea.

Mr. RABEN. No.

Mr. LENNON. No.

Mr. NORTON. Yes.

Ms. DEGETTE. OK. And how do you know that, if you didn't talk to the staff, Mr. Norton?

Mr. NORTON. The exhibits that were provided to me obviously support the——

Ms. DEGETTE. Well, take a look——

Mr. NORTON [continuing]. Summary of the documents that you——

Ms. DEGETTE [continuing]. Mr. Norton, at Exhibit B5——

Mr. NORTON [continuing]. Have identified——

Ms. DEGETTE. No. I am talking about——

Mr. NORTON [continuing]. Ms. DeGette.

Ms. DEGETTE [continuing]. The staff——

Mr. NORTON. I am just trying to answer your question.

Ms. DEGETTE. Mr. Norton, I am talking about the staff-created documents like the charts. Did they tell you what data they used in creating the staff-created documents?

Mr. NORTON. That is not what you asked, but the answer to that——

Ms. DEGETTE. Yes, it is what I asked.

Mr. NORTON [continuing]. Is no.

Ms. DEGETTE. Thank you. Ms. Foster?

Ms. FOSTER. No.

Mr. SUKHIA. No.

Ms. DEGETTE. Thank you. Now, Mr. Raben, I want to ask you a couple questions. Given that no witness on the panel has first-hand knowledge of how these exhibits were created or the underlying facts captured in any of them, do you think it is appropriate for the witnesses to speculate about possible criminal misconduct based on those documents?

Mr. RABEN. I think calling it speculation is entirely accurate. It would be pure speculation. It wouldn't be probative.

Ms. DEGETTE. Now, you heard in his testimony, you heard Mr. Lennon testify that, based on his experience as a prosecutor, that

he believed that these documents, in and of themselves, not only establish probable cause but proof beyond a reasonable doubt. What is your opinion of that analysis?

Mr. RABEN. I would be a little frightened if that were the regime in which——

Ms. DEGETTE. Why?

Mr. RABEN [continuing]. We live.

Ms. DEGETTE. Why?

Mr. RABEN. Well, several reasons. One, the context in which all of these facts come, and I don't have to go back to 2000, although I do think that is illustrative, just in the last——

Ms. DEGETTE. If you can just be brief, I only have 5 minutes.

Mr. RABEN. There has been a volume of inaccurate and deceptive information thrown at committees and the media about this issue. If I were an investigator or prosecutor looking at it, I would be extremely skeptical, and I would want to know more before I proceeded.

Ms. DEGETTE. And wouldn't you want to bring in the people that actually created those documents——

Mr. RABEN. Clearly.

Ms. DEGETTE [continuing]. And put them under oath?

Mr. RABEN. Yes.

Ms. DEGETTE. Thank you. Now, Madam Chair, the reason why I am kind of stuck on this is because, if people are selling fetal tissue in violation of the law, we need to get to the bottom of it. We need to find it out. But we can't just have some witch hunt based on some things that were taken off of screenshots and off of documents and charts created by staff.

And I will tell you, even though 12 States—including my home State of Colorado, by Attorney General Cynthia Coffman, who is a Republican, who investigated these claims Mr. Norton was talking about against Planned Parenthood of the Rocky Mountains, and found no cause of action to investigate—even though 12 States have investigated and found there was nothing, if you want to send it to the Department of Justice for investigation, I will guarantee you they won't make up little charts with their staffs.

They will get to the bottom of it with original documents, and I suggest that is what you should do if you think there is a criminal violation.

I yield back.

Mr. NORTON. That is not correct about Colorado Attorney General Coffman, Ms. DeGette.

Mrs. BLACKBURN. The gentlelady yields back. Her time has expired.

Dr. Bucshon, you are recognized for 5 minutes.

Mr. BUCSHON. Thank you. Mr. Norton, do you want to expand on that about the Attorney General quickly?

Mr. NORTON. Yes. Attorney General Coffman has not investigated the allegations of Rocky Mountain Planned Parenthood or other Planned Parenthood facilities around the country in trafficking in baby parts of bodies.

She has taken the position she has no authority to investigate the matter whatsoever.

Mr. BUCSHON. Than you.

Mr. NORTON. Unless asked by the Governor to do so, with the Governor as a——

Ms. DEGETTE. Will the gentleman yield?

Mr. NORTON [continuing]. Supporter of——

Mr. BUCSHON. I will not yield.

Ms. DEGETTE. Well, then, I guess we won't get to the truth of it.

Mr. BUCSHON. Thank you. A couple things. First of all, you know, the indictment in Texas was for using a fake ID. And I am the dad of a couple of college students, and I can tell you, you know, half the college campuses would be indicted over that.

Also, it was stated that researchers are losing money on this fetal tissue. If they are losing money, how are they losing money if there is not a financial transaction?

The other thing is, I agree that past investigations are completely irrelevant to today's discussion. You know, if that was the case, we would never investigate anything. And the other thing is, the person in Colorado who tragically murdered some people had very severe mental illness, and that was what impacted that situation, which s tragic.

During the time of the 1993 NIH Revitalization Act, everyone had high hopes about fetal tissue transplantation. Just so you know, I was a doctor before I came to Congress. Unfortunately, that didn't work out. And so, in reference to this particular procurement agency, which has been mentioned multiple times by the minority, this whole section of the Act was passed to reverse the ban on fetal tissue transplantation.

The statute which applies to all fetal tissue allows reasonable payments associated with transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. I know a little bit about this because I was a doctor, and it appears to me that all of these are upstream activities from the abortion clinic in reference to this particular full-service procurement agency.

So the question is, I am going to—I will start with Mr. Lennon. Assuming that that is correct, under this particular procurement agency we are discussing today, do you see any language in the statute that forms the basis to reimburse the abortion clinic for any costs at all?

Mr. LENNON. I don't—the statute itself doesn't delineate between the two, but I would want to quickly respond to Mr. Raben. My written testimony submitted makes clear that there were assumptions made, that all this evidence is admissible in court, and that an ethical prosecutor would also have storytellers, either credible insiders or people who are compelled to testify to support this.

So my analysis—and the question, I think, was unfair. My written testimony points out that this evidence needs to be corroborated.

Mr. BUCSHON. Understood.

Mr. LENNON. But I do think that if the abortion clinic was able to show that there were reasonable costs that were delineated there—and I have seen no evidence of that—then that would be complying with the statute. But I didn't see that in any of the exhibits I was asked to review, and that is the basis of my opinion.

Mr. BUCSHON. Mr. Norton?

Mr. NORTON. Yes, I would agree with that. I think that there are a fair number—first of all, let me say that in our system of criminal justice, each and every individual is presumed innocent unless and until proven guilty beyond a reasonable doubt. Even those clients Ms. DeGette would bring to my office when I was United States Attorney, they would be presumed to be innocent as well from the get-go.

Mr. BUCSHON. Agreed.

Mr. NORTON. And so that would be the case here, and so there are a number of unanswered issues I think that a competent investigation could and should pursue. For example, how much does the abortion clinic receive for an abortion from a client? And what is the source of that? Is it from the patient, from insurers, from Medicaid, from other sources?

What, if any, of the services that are provided to the abortion client—that is, the woman upon whom the abortion is committed—are unbundled and billed to insurers, including Medicaid? What is the actual cost of the abortion? What are the amounts over and above that cost? And where do they go, and how are they accounted for? In other words, what is happening to those profits?

How does the abortion clinic notify the procurement business or procurement business technician of the fact of abortions? It appears from the materials we were provided that the procurement business technician is actually embedded in the abortion clinic and is given access to confidential medical records before the patient even shows up on the scene, so that that technician can select what organs the company seems to want at that point in time.

Mr. BUCSHON. I am running out of time, so I am going to have to—Mr. Sukhia, you wanted to comment on something earlier. Real quickly.

Mr. SUKHIA. Well, thank you very much. The Federal provision is a Federal provision. So all the talk about, well, States having looked at this——

Mr. BUCSHON. By the way, the States that looked at it, the services in question here weren't provided in the first place. And I will speak for Indiana, so, obviously, nothing was done wrong because that wasn't even part of the equation.

Mr. SUKHIA. Well, so there are different jurisdictions, and from a Federal standpoint, from the standpoint of a Federal prosecutor, he is not going to be swayed by what some States decided was or wasn't a violation of their State statutes.

Mr. BUCSHON. Fair enough. I yield back.

Mrs. BLACKBURN. The gentleman's time has expired. Ms. Speier, you are recognized for 5 minutes.

Ms. SPEIER. Thank you, Madam Chair. You know, this hearing belongs in a bad episode of "House of Cards." I am sure Frank Underwood is lurking somewhere here in the room. In fact, this hearing is literally based on a house of cards, and the exhibits being used as a foundation are, in all likelihood, the product of a theft carried out by someone who is now under indictment in Texas and whose home has been the subject of a court-ordered search in California.

Is this hearing really going to proceed based on stolen and misleading documents? Even Frank Underwood would be blushing at this point. This committee's sole purpose is to hold fake trials of citizens and companies that comply with laws but not with the political agenda of Republicans who want to restrict women's health care. Twelve States and four Congressional committees—one Senate, three House—have already investigated the videos released by the so-called Center for Medical Progress last summer and found absolutely no evidence of wrongdoing.

The same cannot be said for David Daleiden and his associates. This so-called committee is the very definition of a kangaroo court, a mock court that disregards the rules of law and justice to validate a predetermined conclusion. But this mock court has real consequences. While we are focusing on what goes on inside a woman's uterus, we are completely ignoring what happens to babies and children outside of them.

How else can you explain why this Panel is holding this hearing while children go hungry and research on pediatric cancer is desperately in need of more research dollars? What about the health implications for our children if we stifle fetal tissue research? After all, fetal tissue research was key to the CDC's recent confirmation of the link between Zika and microcephaly. This is the first step in developing treatment options and vaccines to stop the spread of Zika.

Considering Zika-affected infants suffer from brain damage, severe seizures, and other medical problems, why aren't we talking about protecting those infant lives? If this committee succeeds in abusing medical professionals so severely that they abandon promising research, not a single life will be saved, but many, many will be lost. Perhaps we should propose a new name for this committee: the Select Investigative Panel on Stopping Research and Letting People Die.

Now, let me ask Mr. Raben, given that no witnesses on the panel have firsthand knowledge of how these exhibits were created, or the underlying facts captured in any of them, do you think it is appropriate for the witnesses to speculate about——

Mr. BUCSHON. Will the gentlelady yield?

Ms. SPEIER [continuing]. Criminal misconduct based on those documents?

Mr. BUCSHON. Madam Chairman?

Mrs. BLACKBURN. The gentleman is recognized.

Mr. BUCSHON. I take personal offense to it being said that, as a physician, I am here to allow people to die. I would like those words stricken from the record. It is a personal attack on me as a physician.

Ms. SPEIER. You were not referenced by name.

Mr. Raben, will you please respond?

Mr. RABEN. I don't—I wouldn't quibble with——

Mr. BUCSHON. Inquiry on that?

Ms. SPEIER. You have to be referenced by name.

Mrs. BLACKBURN. If the gentlelady will yield.

Ms. SPEIER. I will yield.

Mrs. BLACKBURN. Thank you. You would have to be referenced by name. And I appreciate the inquiry, but you would need to be referenced by name.

Mr. BUCSHON. Thank you. I would just like it part of the record that I am offended by that comment. Thank you.

Mrs. BLACKBURN. The gentleman is so noted.

Ms. SPEIER. No offense intended.

Mrs. BLACKBURN. Ms. Speier, you are recognized.

Ms. SPEIER. Mr. Raben?

Mr. RABEN. Thank you. I can't quibble with speculation. It is important that everybody remember that it is just speculation, that this is not probative evidence of anything. We have got very, very bright, experienced people speculating.

Ms. SPEIER. So to Mr. Lennon: Madam Chair, even in her opening remarks, referenced "horrible videos." These videos have 30 minutes missing from them. The doctor interviewed said 10 times that Planned Parenthood does not profit from tissue donations, and Mr. Daleiden sent a proposed transfer agreement with a specific clause, a compensation clause, to Planned Parenthood when he was trying to negotiate a contract.

Planned Parenthood struck that particular compensation clause, and then Mr. Daleiden didn't pursue it. Is that a reputable person on which to base an entire committee hearing?

Mr. LENNON. I have never met the gentleman that you refer to. In fact, I don't know what "House of Cards" or Frank Underwood is, either. But I will tell you this: There is a difference between a discredited whistleblower, like Ms. Clayton unfortunately had to deal with, as opposed to admissions made by an agent of a potential target.

So those are apples and oranges. I have not purported—I am not saying I have watched all of the videos. I have seen some excerpts. I am just talking, as an evidentiary matter, there is a huge difference between a whistleblower who is discredited and an agent or director or employee or officer of a targeted industry. Those are admissions that could be admissible in court.

So I think—again, I don't want to opine. I have not looked at all of the videos. I don't even know where they were all——

Ms. SPEIER. Thank you. My time has expired.

Mr. LENNON. Thank you.

Mrs. BLACKBURN. The gentlelady yields back.

Dr. Harris, you are recognized for 5 minutes.

Mr. HARRIS. Thank you very much.

Look, I am sorry, I am not a lawyer. I am a doctor. I have worked, you know, in NA-sponsored research and at Johns Hopkins. And I want to ask today not about profit, because, look, I think the record speaks for itself. All of the costs were covered by the procurement companies. The record speaks for itself.

On Exhibit B2, the procurement company's brochure, it says that, you know, these are IRB-certified consents. Exhibit C8, page 2, at the bottom says "BioMed IRB Approved," and in fact I am going to ask a legal question here because, you know, IRB approval is very important in human research.

And if you are looking at whether someone is out to make a profit, they are going to cut corners, they are going to save a dollar

here or there, and so I am going to ask a question about specifically this company called BioMed IRB.

And I am going to ask, Madam Chair, to enter into the record two letters from the Department of Health and Human Services regarding the company, one from March 29, 2012, the other from January 16, 2013.

[The information appears at the conclusion of the hearing.]

The March 29, 2012, letter actually is a letter to that company basically asking it to cease and desist from doing approvals or, in fact, anything being obtained under one of their approvals because of the shoddy work that this apparently one-room, single-owner IRB mill. That is the best way you can call it. Look, you can go to their Web site, you can see their price list.

You know, I have submitted things to an IRB. They guarantee that if you have it in by Tuesday before noon, you are actually going to have it before the IRB and approved that week, basically. But for $1,900 more, you can actually submit it after noon on Tuesday and have it approved that week. It is unbelievable.

But I want to ask a specific legal question, because if in fact the company continued to obtain specimens under that IRB approval between March 29 and January 16, 2013, who is liable for that, if in fact when that IRB—when the FDA said, "You cannot obtain specimens," told the IRB that that is true. Mr. Lennon, who would be responsible for that?

Mr. LENNON. I don't think I have a foundation to answer that question.

Mr. HARRIS. OK. Let me ask you a question: Is it a valid question to ask that, in fact, if the FDA had said you can't obtain tissue—you can't obtain anything under the IRB approvals that you have had until you have responded to us—and the letter came back almost a year later, if in fact a procurement company was obtaining tissue in that period of time, would that be a problem because Title 45 of the Regulations Part 46 make it pretty clear you need IRB approval? And, in fact, downstream Federal research, where an IRB further downstream depended upon that information in that IRB to be accurate. In other words, if I was obtaining, as a researcher, tissue from this company, my IRB assumes that the previous IRB approval is actually valid, that in fact that company represents they have IRB approval.

If they don't, is it valid to actually look downstream and see whether those IRBs were notified downstream, whether in fact those researchers were notified that this IRB approval in fact had been suspended by the FDA? Is that valid? Is that something we should look into? Mr. Norton, something we should look into?

Mr. NORTON. I think that is a very valid question, frankly. And as I looked at the exhibits in preparation for this hearing, that was a question that I had: Exactly what was the effect of and the date of and the integrity of the IRB approval process? As I understand Exhibit C15, it is a document that is being provided to the woman who is——

Mr. HARRIS. Yes. Let me go on and——

Mr. NORTON [continuing]. Obtaining the abortion. So I think it is a valid—because essentially it is a false statement by——

Mr. HARRIS. And let me go further to a false statement. On the videos, pretty clearly a doctor says, "We modify the procedure to get better body parts." Pretty clearly. I mean, look, there is no doctoring going on here. This is, you look at it—and I urge anyone looking at this hearing, go look it up. The doctor says, "We alter it to preserve the calvarium, so we don't crush the calvarium, so we can actually get the amount of money we are going to charge for it."

The Federal regulations say you actually have to tell the patient if you are going to change a procedure. Now, I look at the consent forms, which is Exhibit C8, page 2, it says specifically, "your abortion procedure will not change in any way." We look at one of the consent forms that was actually entered into the record last time, which says that your procedure will not be changed in any way.

If in fact the procedure is changed in any way, is that a violation of the IRB-approved consent which is necessary for Federal research dollars? It is actually necessary for any research to be conducted downstream. Is that a violation of that, if you in fact modify the procedure after the patient signed a consent that said "procedure will not be modified"?

Mr. NORTON. Yes. I think that is also a violation of the statute itself.

Mr. HARRIS. Thank you very much.

Mr. RABEN. May I——

Mr. HARRIS. I yield back.

Mr. RABEN. May I just get in there to question the premise?

Mr. HARRIS. My time has expired. I am sorry.

Mr. RABEN. Well, mine has not. The premise of——

Mrs. BLACKBURN. The gentleman's time has expired.

OK. Let's—Mr. Raben, go ahead.

Mr. RABEN. I was going to question the premise of the "I don't know a thing about the consent forms at IRB." I never work on IRB, but your premise that this part of the video was not distorted is not accurate. Every aspect of the videos that were put out in the public were heavily edited, deceptive, and distorted, and independent analysis finds—and I don't think there is a sane prosecutor in the country that would feel comfortable putting people who created those videos on a witness stand in a case, because they would be impeached.

Mrs. BLACKBURN. Ms. DelBene, you are recognized for 5 minutes.

Ms. DELBENE. Thank you, Madam Chair. This hearing and, frankly, this entire investigation, is nothing more than an attempt to limit a woman's right to choose under the false guise of illegal tissue sales. And this isn't the first time we have seen this.

As Ms. Clayton stated, 16 years ago the House held a hearing on nearly identical allegations. Those claims, also based on secretly recorded videos by anti-choice extremists, were found to be fabricated and patently false. In fact, much of the so-called evidence that was used back then mirrors what we are seeing right here today.

In that hearing, the majority relied upon a whistleblower who claimed that the entities were profiting from illegal tissue sales. However, while testifying, the whistleblower acknowledged that he

had fabricated his statements and lacked any knowledge of illegal activity.

The Department of Justice, though, still investigated the person in question, Dr. Miles Jones, and found that, after a thorough review of the issues, no violations of Federal statutes were found. So, Mr. Raben, if the Justice Department had uncovered evidence that Dr. Jones had violated the Federal laws on fetal issue donation, the statute, in particular Section 289g-2, would have permitted the Department of Justice to prosecute. Is that correct?

Mr. RABEN. Yes.

Ms. DELBENE. And the majority appears to be saying that the term "valuable consideration" isn't fully defined and, as a result, the DOJ is incapable of enforcing the law. In your opinion, does the Department of Justice lack the clarity that they need to enforce the law?

Mr. RABEN. No.

Ms. DELBENE. And if the Department had actual evidence of Federal violations in those cases, the DOJ would enforce the law, would it not?

Mr. RABEN. I have complete confidence that the men and women of the Department of Justice know what they are doing and take issues like this seriously. Yes.

Ms. DELBENE. So is it fair to say, then, that there really isn't a problem with the statute in the 2000 case regarding the Miles Jones investigation but, rather, a lack of facts to support the prosecution?

Mr. RABEN. That would be my inference, yes.

Ms. DELBENE. And do you think we are in a similar situation from what you have seen so far today?

Mr. RABEN. Yes.

Ms. DELBENE. So do you think it is possible that the lack of prosecutions that others have referred to over the years under both Republican and Democratic administrations signals that there aren't widespread violations of the law as we have heard alleged here today?

Mr. RABEN. That is right.

Ms. DELBENE. So then, once again, I think this hearing is really another recycled attempt to show wrongdoing when there is none or there is no evidence that there has been, and we are, once again, watching history repeat itself.

You know, I would also point out that, after the investigation in 2000, women's healthcare providers were also subjected to false allegations or false accusations on seven separate occasions between 2000 and 2013, all based on so-called evidence from anti-choice extremists. I don't know, Ms. Clayton, if you have any comments you want to make about those allegations that took place afterwards.

Ms. CLAYTON. I would be glad to. The false allegations and the attempts to stir up crazy people like Robert Dear have been ongoing. I think they have been ceaseless. In fact, anyone who saw Mark Crutcher talking at the Cleveland Right to Life last month saw him brag about stirring up people like Daleiden who will go out and do his business by any means necessary. How Crutcher has avoided prosecution, I don't know, but I think it is because he gets other people to lie for him.

These efforts by the radical anti-choice groups like Life Dynamics, Army of God, have been endless, as far as I can tell, and they threaten the lives of everyone who uses a clinic for—and the clinics, by the way, don't provide just abortions, they provide a host of health services. The people who were murdered in Colorado weren't getting abortions. It is a terrible threat to the health and safety of the Nation when these people are allowed to get away with that.

Ms. DELBENE. You know, the majority seems determined to use this taxpayer-funded panel to continue pursuing the latest series of false, unsubstantiated allegations, even though they have been debunked by everyone who has looked at them, including State attorneys general as well as committees right here in Congress.

So the truth is that the investigation, and this particular investigation, isn't really about fact-finding at all. As we have talked about, we haven't had witnesses who can speak to the facts here. So these are just baseless allegations made by David Daleiden, and it is just another attempt, I would say, to smear women's healthcare providers with falsehoods and fabrications. Women definitely deserve better.

I yield back, Madam Chair.

Mrs. BLACKBURN. I thank the gentlelady.

Mr. Duffy, you are recognized for 5 minutes.

Mr. DUFFY. Thank you, Madam Chair. Is it fair to say that the whole panel today thinks that we should look for the truth? Anybody disagree with that? Raise your hand if you disagree with that.

OK. And we should actually enforce the law. Does anybody disagree with the fact that we should enforce the law? Because we all—all right. Great. We are starting out very well.

I have heard some conversation about how the Department of Justice and investigations and so, just to be clear on this, Ms. Clayton, has there been an FBI investigation into this issue?

Ms. CLAYTON. I am not privy to that sort of thing. I have no idea.

Mr. DUFFY. OK. So how about this? Is there a lead DOJ attorney that has been assigned to lead the investigation into this matter?

Ms. CLAYTON. Mr. Duffy, I am a civil litigator. I have no knowledge or access to that sort of information——

Mr. DUFFY. But just——

Ms. CLAYTON [continuing]. Which I understand has to be kept—I don't think it is allowed to be shared with people like me.

Mr. DUFFY. So you are not aware of any lead attorney at the Department of—does anybody on the panel know of a lead attorney at the Department of Justice who is leading this investigation?

Mr. SUKHIA. No. I have heard nothing of——

Mr. DUFFY. I haven't, either. I want to have the panel refer to Exhibit B2 and B3. Starting with B2, I believe that this was a document that was received from a national abortion provider conference, and it seems to indicate that there could be financial profitability for an abortion provider if they engage with the blocked-out middle person, right?

So, if we look at the statute, it prohibits "valuable consideration" to be paid for the transfer of body parts, is that right?

Mr. SUKHIA. Absolutely.

Mr. DUFFY. And so if someone is getting reimbursed for a body part, it is pretty tough to make a profit, isn't it? If you are just get-

ting reimbursed, you can't make money. Am I missing something, Mr. Sukhia?

Mr. SUKHIA. I agree, totally.

Mr. DUFFY. OK. But if you are getting more than just reimbursement, you can make a profit.

Mr. SUKHIA. Yes.

Mr. DUFFY. Does that concern anybody on the panel that then maybe the DOJ and the FBI isn't looking into this? Mr. Norton?

Mr. NORTON. I think that is highly concerning. That is why we are here, to encourage this panel to do that.

Mr. DUFFY. I would agree with you.

Ms. Foster, I have heard a lot of my friends across the aisle talk about this being an issue of women's health care. In regard to 42 U.S.C. Section 289, this is a section I believe that talks about valuable consideration for fetal body parts. Is there anything in that section that you are aware of that relates to women's health care?

Ms. FOSTER. There isn't. And I would add that as a woman and, in fact, as a post-abortive woman, I am deeply offended that abortion clinics are permitting improper access by procurement businesses to really exploit us, to potentially place us under duress, and to put our children on display for sale in the way that chicken livers are in a grocery store. It deeply offends me.

Mr. DUFFY. Thank you. Ms. Clayton, I am sure you have had a chance to look at Exhibit B2. Is it your testimony that this document has been altered in any way?

Ms. CLAYTON. B2? I have no knowledge of any of these documents. And if these documents are anything like the videotape, I would start with the assumption that they probably have been altered, but I don't have any personal knowledge one way or the other. I never saw them until they were sent to me by email. I think it was yesterday.

Mr. DUFFY. So you have had a chance to look at them since yesterday, you are an impartial witness today who is making assertions that they are probably doctored.

Ms. CLAYTON. No. I said I would start with the assumption that they might be because——

Mr. DUFFY. Well, take a look at them. Tell me what——

Ms. CLAYTON [continuing]. I have no knowledge of them, nor has anyone in this room given any indication of the source of the document.

Mr. DUFFY. Look at the document.

Ms. CLAYTON. So as far as I know, they might have been invented——

Mr. DUFFY. Ms. Clayton, this is my time.

Ms. CLAYTON [continuing]. Just like the videotape had been——

Mr. DUFFY. I would love to see—tell the Panel today, what has been doctored in Exhibit B2?

Ms. CLAYTON. Exhibit B2?

Mr. DUFFY. This is the document that shows that——

Ms. CLAYTON. Let me find it.

Mr. DUFFY [continuing]. An abortion provider can have financial profitability.

Ms. CLAYTON. Well, actually, no, it doesn't say that at all. This obviously refers to adult tissue, as well as any other kind. This is

not limited. I looked at B2, sir, and it is clear that this is talking about adult tissue, which is far differently regulated——

Mr. SUKHIA. That is not true. It is talking about fetal tissue. It is clearly——

Mr. DUFFY. It says fetal to adult tissue.

Ms. CLAYTON. It says fetal and adult——

Mr. DUFFY. Right on its face. It wasn't doctored enough.

Mr. SUKHIA. Stem cell-rich blood.

Ms. CLAYTON. It has been redacted in certain ways that I can't tell what has been redacted.

Mr. DUFFY. Right here, fetal DNA.

Ms. SPEIER. Will the gentleman yield?

Mr. DUFFY. No, I will not.

Ms. SPEIER. OK.

Mr. DUFFY. And it also talks about "stem cell rich blood and raw materials." Does anybody know when they say "raw materials" what that is referring to?

Ms. CLAYTON. Perhaps adult tissue. It certainly applies to both adult and fetal, and I can't tell from the——

Mr. SUKHIA. Well, even if it does apply to both, it is still an offense because it does apply to fetal.

Mr. DUFFY. If this document is being sent out during the national abortion provider conference, and they are talking about adult tissue, is that your testimony today, Ms. Clayton, we are not talking about fetal tissue?

Ms. CLAYTON. Is what my testimony?

Mr. DUFFY. That this document is referring to adult tissue when it is being provided to the appropriate——

Ms. CLAYTON. I have no idea. All I can—

Mr. DUFFY [continuing]. National abortion provider conference.

Ms. CLAYTON. Sir, all I can tell you is that it is clear from reading this document that it is not limited to fetal tissue and——

Mr. DUFFY. One last——

Ms. CLAYTON [continuing]. And, sir, if I may finish answering——

Mr. DUFFY. One last question. I have one last question.

Ms. CLAYTON [continuing]. The regulation——

Mr. DUFFY. One last question.

Ms. CLAYTON [continuing]. Are entirely different.

Mr. DUFFY. There has been a lot of conversation on the Hill about——

Mrs. BLACKBURN. The gentleman's time has expired.

Mr. DUFFY [continuing]. Money involved in politics. Has anybody on this panel made any——

Mrs. BLACKBURN. The gentleman's time has expired.

Mr. DUFFY [continuing]. Contribution to any of the members that sit on this panel? If so, raise your hand if you have made a contribution. To anybody on the panel.

Mrs. BLACKBURN. The gentleman's time has expired.

Mr. DUFFY. I yield back.

Mrs. BLACKBURN. Mrs. Watson Coleman, you are recognized for 5 minutes.

Mrs. WATSON COLEMAN. Thank you very much. It is often said that Congress writes the laws and the executive branch enforces

them. In 2000, when very similar allegations about tissue procurement organizations were made based on explosive video interviews, the Justice Department was asked to investigate.

Then-Assistant Attorney General Robert Raben—you, sir, thank you for being here—responded to a request from Fred Upton, who had inquired about the potential criminal violations of the Federal statute against fetal tissue sales. In that letter, the Department noted that "based upon a preliminary review of our records, it appears the Department has not received any information meeting our standards for triggering a formal investigation that fetal tissue has been sold for profit." And I ask unanimous consent that a copy of that letter be entered into this record.

Mr. Raben. Thank you, Madam Chair.

Mrs. BLACKBURN. So ordered.

[The information appears at the conclusion of the hearing.]

Mrs. WATSON COLEMAN. Mr. Raben, can you explain what the standards for triggering a formal investigation are within the DOJ and why these standards are necessary, and have these standards been met in this instance that we are debating now?

Mr. RABEN. Why these standards have not been met?

Mrs. WATSON COLEMAN. What the standards are.

Mr. RABEN. Yes.

Mrs. WATSON COLEMAN. Why should they be met?

Mr. RABEN. Right.

Mrs. WATSON COLEMAN. What triggers this? And are we there now?

Mr. RABEN. Extremely briefly, there are different levels that all investigative and prosecutive agencies go through. There is an initial investigation, which can be begun with, you know, any credible data. There is a formal investigation, which requires a supervisor to sign off for the use of resources, and then it is working with a prosecutor to figure out whether, with a whole range of criteria, including sustainability of a conviction, are there other jurisdictions that could take it.

So I can refer you to the AG guidelines and the FBI guidelines, and I can get that to you subsequently. But to answer your question, it could well be that an agency is involved in an investigation. We have on the record 12 States that have opened an investigation and closed. We have on the record 8 State officials saying they wouldn't even open an investigation based on the evidence that they have.

So I wouldn't be surprised if the Department has looked at it and declined. And as I have stated before, the central problem is there is so much duplicity and deception around how so much of this evidence was created that I think it would give most prosecutors pause to go forward with a case.

Mrs. WATSON COLEMAN. So as in the Daleiden videos, the deceptively edited videos, and sort of the out-of-context invoices, would they be enough to trigger a DOJ investigation?

Mr. RABEN. It would be an investigator and a prosecutor going with incredible caution. He or she would have to find, in my view, probative and credible evidence from other than that source.

Mrs. WATSON COLEMAN. Right. And so would it involve also determining the validity of the Daleiden allegations?

Mr. RABEN. It is bad facts. If——

Mrs. WATSON COLEMAN. So it would be—I am sorry.

Mr. RABEN. No, no. Go ahead.

Mrs. WATSON COLEMAN. Thank you. So it would be important to at least have the conversation with individuals with actual knowledge of the facts contained in any documents under review.

Mr. RABEN. Yes.

Mrs. WATSON COLEMAN. Any requests or investigations.

Mr. RABEN. Yes.

Mrs. WATSON COLEMAN. Here today you have been asked by my Republican colleagues to opine about possible criminal misconduct based on a slew of documents that were sent to you late Monday afternoon without identification of the author of any document, underlying source of information the documents contained, and without the benefit of speaking to anyone with firsthand knowledge of that information.

Is this, in your opinion, a fair or legitimate way to determine if there has been a violation of Federal law?

Mr. RABEN. No.

Mrs. WATSON COLEMAN. Madam Chair, unlike the Select Panel's investigation, DOJ must base its investigations on real facts and hard evidence. This Panel has, instead, based its investigation—and I put that in quotations—so far on an indicted extremist and his discredited videos, and it is certainly a time for the majority to rely on facts, not inflammatory allegations of anti-abortion extremists.

And with that, I would just like to ask Ms. Clayton one question, and that has to do with adult tissue versus fetal tissue. You wanted to say something with regard to that, and I want to give you that opportunity, because it is clear that, wherever that particular slide comes from, it does refer to both.

Ms. CLAYTON. OK. From my experience 16 years ago representing a foundation that provided both fetal and adult tissue for medical research, I know a little bit about it. My knowledge is out of date, but among the things I know are that fetal tissue donations are highly, highly regulated, as are donations of fetal or adult for transplants, very highly regulated.

When it comes to adult tissue that is just for research, there are still regulations, of course, but far fewer. So when I looked at that exhibit—what was it, B or something?—I immediately saw the exhibit, assuming it is a real document, was conflating more things than one. It wasn't just about fetal. It was——

Mrs. WATSON COLEMAN. It was about a range of services.

Ms. CLAYTON. Yes. And so if you talk about what you can—if I die on the Amtrak and my liver goes to somebody, you know, they can do a lot of things with that, not highly regulated.

Mrs. WATSON COLEMAN. Thank you, Ms. Clayton. Thank you, Mr. Raben.

Thank you, Madam Chair.

Mrs. BLACKBURN. Thank you. The gentlelady yields back.

Mrs. Hartzler, you are recognized for 5 minutes.

Mrs. HARTZLER. Thank you, Madam Chairman. Nobody should make a profit from the sale of baby body parts. That is something that is shared by the majority party as well as the minority party.

I want to remind everybody that back in 1993 when this was first introduced in Congress, the idea of this, Henry Waxman, who introduced the amendment, a Democrat, said it would be abhorrent to allow for sale of fetal tissue and a market to be created for that sale.

And yet today we have seen that the procurement organizations in Exhibit 1, 2, 3, and 4 are receiving $700 to $850 per brain. But I want to focus on the abortion clinic's part in this. Could we look at Exhibit D1? Here are the payments that we have obtained to various abortion clinics for these baby body parts. We have Fresno having 38 specimens, and they received $2,090. Sacramento abortion clinic received $3,740, San Jose $3,575.

Now, nationwide the Panel investigation has found that there are many more of these middleman procurement organizations, and there are hundreds of abortion clinics. And I remember some of the abortion clinic doctors on the video that Mr. Sukhia referenced talking about making money from the sale of baby body parts, even joking about it.

So I want to hear from the former U.S. Attorneys, given their training and experience, how they would investigate the accounting records and anything else to document whether the abortion clinics profited for the sale of baby body parts.

So, Mr. Sukhia?

Mr. SUKHIA. Yes, ma'am. Thank you. I have some experience both on the prosecutive side of this, not just being a former prosecutor for 13 years as an AUSA, and then a few years as a U.S. Attorney, but also in my experience fighting Planned Parenthood in a very grueling eight-day trial, one of the few in the country, on the defense of Florida's Parental Notice of Abortion Act.

And I will tell you that "follow the money" is a concept that applies with special force in that area. And it was astounding what I learned about how money motivates that industry. And when I look at these figures—let me give you an example. One of the doctors that testified acknowledged that he had performed over 100,000 abortions, and we—based on the amount of time that he—the one way we could do it, because I continued to try to find out how much are they making. And they fought tooth and nail to prevent that information from coming out.

So to quickly just answer your question, I would say, yes, it is extremely important to find out where the money——

Mrs. HARTZLER. What specific documents would you look for?

Mr. SUKHIA. I would ask for bank records.

Mrs. HARTZLER. OK.

Mr. SUKHIA. I would find out what—you know, follow the money. I would find out, you know, who is getting paid, where are the checks going?

Mrs. HARTZLER. OK. Thank you. Mr. Norton?

Mr. NORTON. Yes. I would do the same. First of all, I would start by looking at the videos, which I have seen. I would start by reading the forensic accounting report by Coalfire Investigations made up of former FBI agents, which found that the videos were credible and the redacted versions say what the longer versions say.

I would obtain the accounting records, the financial records of the abortion clinic, of the procurement business, and, frankly, I

would obtain the records of the end user as well, and subpoena both records and witnesses from all of those entities to flesh out the facts in this case, which I think are there.

Mrs. HARTZLER. Thank you very much. In the last minute, I want to turn to Ms. Foster and ask you a question. As you have just testified, a post-abortive woman, please explain a little bit more about what you think regarding possible HIPAA violations that Mr. Norton raised, where the procurement tech has the ability, after receiving the order through email in the morning, to review the medical records of the patients without their knowledge, explain what you think. Has HIPAA been violated? And, if so, what should the penalty be?

Ms. FOSTER. I am very concerned that HIPAA may have been violated. Obviously, Planned Parenthood has gone to court time and time again to keep secret and confidential the records of women who have abortions, and yet these very same abortion clinics are allowing procurement businesses into their doors, sharing records, and allowing them to find out some of the most personal healthcare information imaginable. So that obviously is an extreme concern for me and something that I definitely want investigated.

Mrs. HARTZLER. Thank you for sharing that. Certainly, we are here because we care about the women, too. Make sure they are not being manipulated or hurt in any way.

Thank you. I yield back.

Mrs. BLACKBURN. The gentlelady yields back.

Mr. Nadler, you are recognized for 5 minutes for questions.

Mr. NADLER. Thank you, Madam Chair. Just when I think my Republican colleagues cannot find a way to make this investigation more of a farce, we have a farcical hearing like this one. None of the documents the Republicans are showing today contain any evidence of wrongdoing. In fact, these misleading documents, many of which the Republican staff produced themselves with no basis in reality, do not provide any foundation for an investigation of this nature.

Cutting and pasting sections of draft contracts that were never signed or formalized, creating charts and graphs with no analytical basis, and printing off random invoices with no explanation for their contents does not meet the standard of evidence for any court of law, let alone for a Congressional investigation.

I would think the Republicans should have learned this lesson after the mess of a hearing in 2000 when a tissue procurement organization, a TPO, then stood accused of profiting from the sale of fetal tissue research. The source of these accusations: heavily edited videos produced by anti-abortion extremists. Some of the same documents we are looking at today were tossed around by the Republicans in 2000 with the same misrepresentation of the facts.

As we all know, that hearing fell apart when the key witness, Dean Alberty, the man who accused the TPO of profiting from fetal tissue donations, admitted under oath that he had lied in the videos. Suddenly, those invoices and the fee schedules didn't seem like such a smoking gun. Well, they weren't then, and they aren't now, yet here we are again.

This hearing is another example of the Republican majority going to extreme lengths to advance their dual agendas of smearing

organizations against whom all Federal and State investigations have found no evidence of any violations of law, knowing that the smears will endanger the lives of people who work for these organizations, and that is why I have said this committee is worse than McCarthy investigations because McCarthy endangered people's jobs. This committee is knowingly endangering people's lives, and their other goal of eliminating women's choices and degrading their doctors.

Now, Mr. Raben, I would like to ask you a couple of questions. We just received yesterday—just yesterday we received a letter from the counsel for StemExpress who informed us, and I quote, "It appears that the majority staff may have repurposed unauthenticated, stolen documents illegally obtained by David Daleiden and the Center for Medical Progress, and that some of the majority's exhibits have never appeared publicly, suggesting that perhaps the Select Panel may be receiving so-called evidence directly from Mr. Daleiden or his associates."

Does that not call into question the validity of the entire investigation, or at least what the majority appears to be relying on?

Mr. RABEN. It sounds like bad form, yes.

Mr. NADLER. More than bad form, I would think. And what do you think of the refusal by Republicans even to question Mr. Daleiden or to test the credibility and objectivity of his allegations? What should that tell us about this investigation?

Mr. RABEN. I am not going to comment on my good friends across the aisle, their motivation. What I am concerned about is, you know, whether the point of this hearing is to politicize an investigation and to press DOJ to do its job in a way different than they think they ought to do. I think there is a very sad history of that, and it is always dangerous.

Mr. NADLER. A history of using Congressional pressure to——

Mr. RABEN. Yes.

Mr. NADLER [continuing]. Pressure to press prosecutorial decisions.

Mr. RABEN. Yes. It is one thing to refer information and to have comity between the branches; it is another to use politics to pressure a particular agent or investigator into doing his or her job.

Mr. NADLER. In that connection, isn't this entire hearing, this entire investigation, having no purpose essentially other than to suggest that, since it is obvious that these organizations are guilty of what they are being accused of, the DOJ and the various State investigating agencies have not done their job properly if they haven't brought indictments?

Mr. RABEN. That is the implication.

Mr. NADLER. Thank you. And let me ask you this. We have heard before that Mr. Daleiden was indicted only for a false identification, and every college kid—or not every, but half the college kids—have false identification, so big deal. But 18 U.S.C. Section 1001 criminalizes any personal who knowingly submits false material to Congress in connection with an investigation.

And I think, and I would like your comment, from what we have seen and what we have heard in this entire thing, that that does seem to be a serious problem, that Mr. Daleiden and the Center

for Medical Progress were submitting knowingly false information to Congress, and that is a very serious problem.

Mr. RABEN. Yes.

Mr. NADLER. Ms. Clayton, would you comment on that?

Ms. CLAYTON. Oh, yes. I agree completely, and what Life Dynamics admitted back in 2000, I have always wondered why didn't get prosecuted for it because it was an admitted fact by the guy they hired. That is who the DOJ should be going after, if they have time.

Mr. NADLER. In summary, we have the refusal by the committee—who are making all sorts of accusations against StemExpress—we have a refusal by the committee to talk to them, to ask them for explanations. Then we have the committee apparently taking, directly or indirectly, material from Mr. Daleiden, stolen from the StemExpress Web site without asking StemExpress—and that material seems to be doctored, all to say that StemExpress and other similar organizations are doing illegal activities.

But you don't want to talk to them and see if they have an explanation, and you do take apparently false material stolen for that purpose in order to pressure the DOJ. Is that a fair summary of what seems to be going on?

Mr. RABEN. Yes.

Mr. NADLER. Is that a legitimate function of Congress?

Mr. RABEN. I will repeat what I said, that the concern that I have after 20-some years of being on both sides of it is when a Congressional gavel is used to intimidate or pressure an investigative agency to take action that they think ought to be taken, particularly in the face of now 20 States—20 State officials, nonpartisan, have said on the record they have looked into this or related facts and declined to go forward with prosecutions.

Mr. NADLER. Thank you very much. My time is expired.

Mrs. BLACKBURN. Mrs. Love, you are recognized for 5 minutes.

Mrs. LOVE. Thank you, Chairman. And thank you to the panel for being here.

I want to contrast and focus on two different things: organ donations and fetal tissue donations. First, you know, many say that organ donation is a gift that one can give. It is a beautiful thing when you think about somebody donating their organs. And organ donations are done with dignity, disclosure of where and how the organs will be used, and in every hospital in the Nation there are uninfluenced counselors to help with the process, and no money is made from the organ donation. The process is transparent and seen as ethical.

On the other hand, when it comes to fetal tissue donation, it is different. A scared, vulnerable woman, including a minor who is under age, can come into a clinic on the morning of her surgery, and first she needs to give consent to the procedure without any parental guidance or anyone there.

Then, before the event, before this invasive procedure, a tissue technician comes to her and gets her to donate her baby body parts. Instead of an unbiased counselor, the tissue technician may be focused on making a commission, rather than protecting that

woman's best interest. It is not transparent how the fetal organs will be used or by what organization.

To me, the contrast is astounding. It is unethical for this procedure to happen this way. So my question is, Who protects the woman's interest in each case? Who protects the minor's interest in this case? There are no existing laws related to consent for fetal tissue donation.

How many organs are needed? How much will be paid out for each body part? And, as a mother of two teenage girls, I am absolutely astounded and outraged that we don't have laws in place to protect our minors.

Mr. Lennon, why is there uniform law for organ donation in every hospital in this Nation and an entirely different practice for donations of fetal organ tissue?

Mr. LENNON. I don't know, and I would have to speculate. That is a good question.

Mrs. LOVE. Mr.—is it——

Mr. SUKHIA. Sukhia.

Mrs. LOVE [continuing]. Sukhia.

Mr. SUKHIA. Yes. My father was Persian and—he was actually from India, but his people were from Persia. My cousins all say "Kenny, you are pronouncing it wrong, it is Sukhea." But, so Sukhia.

Mrs. LOVE. If there is any evidence that a law is being broken, or suggestions of profiteering from baby organs, should there be investigations to ensure that this is not the case?

Mr. SUKHIA. Yes. And I thought that was the focus of this hearing, which is to ask of a Federal prosecutor, "If you had this information, would it justify a thorough investigation to ascertain those facts?"

Mrs. LOVE. That is right. At the end of your comments, you mentioned that it is actually the duty to investigate to make sure that laws aren't being broken.

Mr. SUKHIA. Yes, ma'am.

Mrs. LOVE. Thank you. Ms. Foster, I want to point out five immediate differences when it comes to organ donation and fetal tissue donation and ask why there would be such a gross difference. And I want to ask your thoughts after you hear these five.

First, organ donation is done with protections and advocates for the donor and/or the person giving consent for the donation of the organs of a loved one sometimes that is already deceased. There is no profit being made, or monies exchanged, with organ donation. Furthermore, if there was any evidence of such, there would be great cause to investigate.

Three, there is never a minor under duress having to make these decisions alone without the consent or advocate of an adult or for any operation procedure, let alone an invasive procedure. Furthermore, a minor would never be in a position to make the decision to donate the organs of another person.

There is no contact, when it comes to organ donation, between the recipient of the organ, the physician procuring the organs, or the transfer team of the consent-giver before the consent is being given. And the HIPAA violations would never be allowed when it comes to organ donation.

So I want to ask you this: If you are ever in a clinic sitting in that room, understanding that those protections are different, who is there advocating for you?

Ms. FOSTER. In an abortion clinic?

Mrs. LOVE. Yes.

Ms. FOSTER. No one.

Mrs. LOVE. No one. Now, furthermore, who is there advocating for a minor who this country would not let get behind the wheel of a vehicle, would not allow to vote, would not allow to join the military, would not allow—be allowed to smoke, would not even be allowed to join a gym because there is a financially binding contract?

Ms. FOSTER. No one.

Mrs. LOVE. No one.

Mrs. BLACKBURN. The gentlelady yields back.

I recognize myself, 5 minutes for questions. And as a reminder to my colleagues, I leave myself until last in the questions, so that everyone is clear.

I want just to go back to a couple of comments that were made, and I do have a couple of questions for you all. The pricing documents, the Exhibits D, we looked at some of those on the pricings of items, brains, things of this nature. If you are looking at a customer paying, say, $2,000 for a brain, and over the course of the year that customer is paying $42,000 for the body parts, it is hard to imagine how the procurement business is operating at a loss.

And what we are seeking to do is to figure out if there is a violation of law, and if someone is selling these fetal tissue parts for a profit. And that is what we are digging down on, is we are looking at the pricing of fetal tissue represented in those D series documents, and that is why we have constructed the chart, the G chart, that shows where there seems to be movement of the money.

So you all have heard this debate. You have heard it from both sides. You have heard the questions coming from both sides. And I am going to start, Ms. Clayton, with you, and work my way down to Mr. Sukhia.

Very quickly, what I would like to hear from you, what documents would you request or subpoena from these procurement organizations in order to find out—we have asked for banking records from the procurement business that has been the point of discussion today, and they have refused to give us those. We thought that would help clear the way, if you will, to figure out what the profiting is.

So let's start there. Very quickly, we have only got 2 minutes and 45 seconds left.

Ms. CLAYTON. I would start with accepting the invitation from the procurement business. I understand its name is StemExpress. And I would have them come in, put them under oath, as I understand they have offered to do, and ask them, How did you come up with this charge? Why is it so much more expensive to——

Mrs. BLACKBURN. That would be an incorrect assumption, but, yes, we would like to have——

Ms. CLAYTON. The second thing I would do is ask them, in each particular case, what aspect of the actual costs does a particular clinic incur? For example, does the clinic provide space? Does the

clinic, as we have seen in your charts, provide the blood draws, which requires a technician, perhaps a nurse, materials? Does the clinic have to do paperwork? And, if so, how much? And, therefore, how much of the actual reasonable cost is incurred by the clinic itself as opposed to by the procurement business?

Mrs. BLACKBURN. OK.

Ms. CLAYTON. That is where I would start.

Mrs. BLACKBURN. OK.

Mr. RABEN. Similar. Sterilization of equipment, what is the cost capital of the equipment, the processing, the preservation, are there transportation costs? I wouldn't look at banking records. I would want to—it is an HR function as well, staff time for the consent forms that are put together.

Mrs. BLACKBURN. All right. Mr. Lennon?

Mr. LENNON. As I said in my opening, if I was a prosecutor, you have to have a forensic evaluation accounting of the procurement business, because that is not clear from the records here. So following the money, you have got to have the entire picture.

Mrs. BLACKBURN. OK. Mr. Norton?

Mr. NORTON. The first thing I wouldn't do is ask the StemExpress or others, "Are you innocent or guilty?" Every defendant I have ever prosecuted or even represented has claimed innocence. That is just not the case. There is some culpability here.

I would do the same thing. I would get forensic accounting. I would get all of the financial records. I would get the profit and loss statements, the income and expense statements, and I would get people under oath before a grand jury. Letters are not particularly valuable.

Mrs. BLACKBURN. Ms. Foster?

Ms. FOSTER. There are two things that I would specifically seek among many different documents. First of all, financial records. That is something that must be brought to light. And, second, women of every generation are unique human beings who can speak for themselves, but the baby body parts profiteers have created a market in which their profits rise if they pressure and coerce women into signing donation consent forms.

So I would want to find out exactly what their procedures are, what documents, what training they have on how to speak to women and how they get those consent forms signed.

Mrs. BLACKBURN. Mr. Sukhia?

Mr. SUKHIA. I would just echo the comments of the other members on the panel. I would note that in the case that I handled, many of the minors were under—there were reports from people who owned and ran clinics that many minors would be under the age of 14 who often would cry out for their mothers, and so forth. They are in no position to give meaningful consent, such as those suggested by the exhibits that were presented here.

Mrs. BLACKBURN. OK. Thank you. My time has expired, and I yield back.

I ask unanimous consent that the members' written opening statements be introduced into the record.

Ms. SCHAKOWSKY. And, Madam Chair, we have provided you a packet of materials to be entered into the record and ask unanimous consent that those be made part of the record.

Mrs. BLACKBURN. So ordered.

[The information appears at the conclusion of the hearing.]

And we also will submit the document binder, ask that that be submitted for the record, and that staff make the appropriate redactions. So ordered.

[The information appears at the conclusion of the hearing.]

We will also submit an article from the Sacramento Business Journal from Cate Dyer, the founder and CEO of StemExpress. That will go into the record with the ranking on StemExpress by biz journals.

[The information appears at the conclusion of the hearing.]

We also would put into the record a screenshot we pulled from StemExpress' Web site just this morning, which still has the fetal tissue sales components in——

Ms. DEGETTE. Madam Chair, have we reviewed that document?

Mrs. BLACKBURN. From this morning? No, you have not.

Ms. DEGETTE. Yes.

Mrs. BLACKBURN. Because we pulled it this morning, but you are welcome to look at it.

Ms. DEGETTE. I would like to look at it.

Mrs. BLACKBURN. Yes. So ordered.

We also have the sourcing of——

Ms. DEGETTE. Well, wait a minute. I am going to reserve the right to object.

Mrs. BLACKBURN. You can reserve the right, and we will come back to that one. We also have the source of exhibits that we will put in the record with the exhibits, so that you will know where they came—there was a question on Exhibit B5, the chart that showed the growth of the procurement business' revenue. That came from business magazine articles and the Congressional Research Service. So that you all are aware of that.

And then there was also a question on Exhibit B4, that chart with the growth in the number of abortion clinics. That information for that chart came from the procurement business owner and a contract with the abortion organization. So ordered.

Ms. DEGETTE. Madam Chair, I withdraw my reservation.

Mrs. BLACKBURN. It is submitted——

[The information appears at the conclusion of the hearing.]

Ms. DEGETTE. But I will also state, I take umbrage at the last statement you made about that last document. It was never ratified. That contract was never ratified. It was a draft. It says that on your specific——

Mrs. BLACKBURN. Right. And the sourcing, this is what we are putting into the record with the document.

Ms. DEGETTE. Well, as you know, we have already litigated that, and I object to them, but, you know, you overruled it.

Mrs. BLACKBURN. With that, the hearing is adjourned, and I thank our witnesses.

[Whereupon, at 12:50 p.m., the panel was adjourned.]

[Material submitted for inclusion in the record follows:]

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON ENERGY AND COMMERCE

April 18, 2016

TO: Members, Select Investigative Panel

FROM: Panel Majority Staff

RE: Hearing on "The Pricing of Fetal Tissue"

On Wednesday, April 20, at 10:00 a.m. in HVC-210, the Select Investigative Panel will hold a hearing entitled "The Pricing of Fetal Tissue." The hearing will focus upon the issues raised as a result of information the Select Investigative Panel has learned about the fetal tissue industry. The witnesses will provide testimony relating to the statute 42 U.S.C. §289 g-2, which prohibits profiting from the sale of baby body parts.

Each perspective will help the Panel understand how the statute applies to the materials produced by the Panel's investigation, as well as whether the statute is adequate.

I. BACKGROUND

On October 7, 2015, the U. S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered it to conduct a full and complete investigation regarding the medical practices of abortion service providers and the business practices of the procurement organizations that sell fetal tissue. This Panel centralized the investigations that were already being conducted by the Committees on Energy and Commerce, Judiciary, and Oversight and Government Reform by bringing them primarily under one umbrella.

History of the Prohibition of Profiting from Fetal Tissue Sales

On March 10, 1993, the U.S. House of Representatives passed an amendment, offered by Rep. Henry Waxman, to H.R. 4, the National Institutes of Health Revitalization Act of 1993. That amendment includes the provisions codified as 42 U.S.C. §§289 g-2(a) and (e)3:

> **42 USC §289 g-2(a) states "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."**
>
> **42 USC §289 g-2(e)(3) "The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."**

During floor debate it was repeatedly stated by supporters of the Waxman amendment that fetal "tissue may not be sold."[1] Rep. Connie Morella expressed her support for the legislation because "fetal tissue could not be sold."[2] Rep. Waxman himself said:

> This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any purpose, just not for the purpose of research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.[3]

[1] 139 Cong. Rec. 1099 (1993) (statement of Rep. John Edward Porter in support of the Waxman Amendment).
[2] Id. (statement of Rep. Connie Morella in support of HR 4 and the Waxman Amendment).
[3] Id. (statement of Rep. Henry Waxman).

The floor debate corroborates Committee Report language. The Report of the Committee on Energy and Commerce on the National Institutes of Health Revitalization Act of 1993 from stated:

> Section 498B prohibits the purchase of human fetal tissue as well as the solicitation or acceptance of directed fetal tissue donations.[4]

The Committee report described the prohibition on the sale of fetal tissue as making the transfer of fetal tissue parallel with donation of other organs under the Organ Procurement and Transplantation Act.[5] But the Committee report adds, "Indeed the Committee has dealt with fetal tissue more restrictively . . . ."[6] The Committee intent is to disallow payment for procurement of any organs.

The intent of the statute is best understood through a simple contrast between two modes of transferring fetal tissue from one entity to another. With the first, an abortion clinic (AC) or middleman Procurement Business (PB) transfers tissue to a researcher, and the researcher may reimburse the AC or PB for its reasonable costs incurred by the transportation, processing, preservation, and quality control of the tissue. With the second, the payment from the researcher exceeds those reasonable costs, enabling the AC or PB to make a profit and thus violates the statute.

The release of videos last summer raised the question of whether ACs and PBs were profiting from the sale of baby body parts, organs and tissues. To profit from the acquisition or transfer of fetal tissue violates 42 U.S.C. §289 g-2, which prohibits the transfer of any fetal tissue for valuable consideration that exceeds the reasonable costs associated with the procurement.

The hearing will explore fetal tissue transfers facilitated by a for profit, middleman PB through its collaborating relationship with a number of ACs. The

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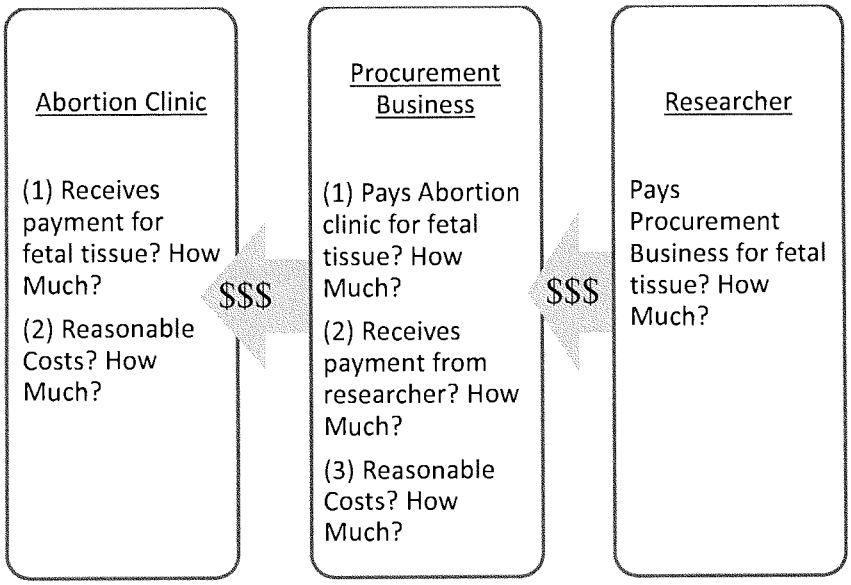
[4] H.R. Rep. No. 103-28 at 76 (1993).
[5] Pub. L. No. 98-507, 98 Stat, 2339 (1984).
[6] H.R. Rep. No. 103-28 at 76 (1993).

PB first performs all of the work necessary to procure, transport, and control the quality of the fetal tissue for the Customer, a researcher. The PB then pays the abortion clinic a per tissue fee for each item it procures. The PB transfers the fetal tissue to the Customer and then receives a per tissue payment from the Customer. The witnesses will be asked whether they believe the current statute is adequate, whether the conduct uncovered by the Panel's investigation may violate the intent of the statute, and whether they have any recommendations.

The graphic below allows a clear understanding of the entities and questions the hearing will explore:



II. WITNESSES

- **The Honorable Ben Sasse**, US Senator from Nebraska.
- **Kenneth Sukhia,** former United States Attorney for the Northern District of Florida, and current senior partner in a law firm.
- **Mike Norton**, Alliance Defending Freedom, and former U.S. Attorney for Colorado.
- **Catherine Glenn Foster**, Charlotte Lozier Institute and Sound Legal.
- **Brian Lennon,** member of a private law firm and Deputy Chief of the Criminal Division for the U.S. Attorney's Office in the Western District of Michigan.
- **Fay Clayton,** member of a private law firm.
- **Robert Raben,** member of a private law firm.

III. ISSUES

The following issues may be examined at the hearing:

- Does the current legislative language adequately prevent profiteering in the sale of fetal tissue?
- Do the payments to abortion clinics for fetal tissue amount to a sale for profit of fetal tissue?
- Do the payments to the middleman Procurement Business from the researcher amount to a sale for profit of fetal tissue?

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact March Bell or Rachel Collins of the Committee staff at (202) 225-2927.

SELECT INVESTIGATIVE PANEL OF
THE COMMITTEE ON ENERGY AND COMMERCE –
114TH CONGRESS
ROLL CALL VOTE # 2

MOTION: Motion by Mr. Duffy to table the motion to exclude the exhibits offered by Ms. DeGette.

DISPOSITION: **AGREED TO**, by a roll call vote of 8 yeas and 5 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mrs. Blackburn	X			Ms. Schakowsky		X	
Mr. Pitts	X			Mr. Nadler			
Mrs. Black	X			Ms. DeGette		X	
Mr. Bucshon	X			Ms. Speier		X	
Mr. Duffy	X			Ms. DelBene		X	
Mr. Harris	X			Mrs. Watson Coleman		X	
Mrs. Hartzler	X						
Mrs. Love	X						

04/20/2016

Hearing on the Pricing of Fetal Tissue

Annotated Index of Documents

Issue

Does the acquisition of fetal tissue by a middleman procurement business (PB) from abortion clinics (ACs) for resale to customers (C) violate the prohibition against profiting from the sale?

I. ***Exhibit A – Rule of Law*** ***Tab A***

Title 42 USC §289 g-2(a) – Requires that no profit be made on acquisition or transfer of fetal tissue.

II. ***Exhibit A-1 – Graphic of Statute: Profit and non Profit*** ***Tab A***

Show the simplicity of nonprofit and profit model.

III. ***Exhibits B1- 6 -- Business Model of the Middleman Procurement Business*** ***Tab B***

The Documents in Exhibit B show the business model of the Procurement Business, its own marketing statements about the product it offers to Abortion Clinics, its marketing trajectory, and its growth since its inception. These document show that the PB constantly sought additional abortion clinics as a source of fetal tissue.

Exhibit B 1 *This is the business model the hearing will discuss*

Exhibit B 2 *This is the company Brochure used to market the PB to Abortion Clinics*

Exhibit B 3 *PB website promoting partnership agreements with Abortion Clinics.*

Exhibit B 4 *Chart showing growth of the PB in number of Abortion Clinics*

Exhibit B 5 *Chart showing growth of PB revenue*

Exhibit B 6 *This is the Contact between the PB and a national abortion organization to acquire an additional 400 clinics.*

IV. ***Exhibit C1-14 The Turnkey Business Product the PB placed inside of Abortion Clinics Tab C***

The "C" documents show, in great detail, that all possible management guidance, tasks, and responsibilities are undertaken by the PB procurement tech employee and that that no tasks are performed by the abortion clinic. Thus, that costs of tissue acquisition are entirely born by entities other that the abortion clinic.

Exhibit C 1 *This is the daily work flow of the PB procurement tech procuring fetal tissue inside Abortion Clinics*

Exhibit C 2 *This is a list of the tasks performed by the PB procurement Tech inside the Abortion Clinics*

Exhibit C 3 *Web site screen grab of how to order any fetal tissue you want*

Exhibit C 4 *Website and phone orders sent to procurement tech via email inside abortion clinics*

Exhibit C 5 *Form the procurement tech uses to check gestation periods so that patients can be matched with orders.*

Exhibit C 6 *Work instructions on procurement given to the procurement tach by the PB for work performed inside the abortion clinic.*

Exhibit C 7 *Procurement Kit provided by the PB*

Exhibit C 8 *PB guidance on obtaining patient consent by procurement tech*

Exhibit C 9 *PB directs it tissue tech to tell the abortion clinic manager what is being procured that day.*

Exhibit C 10 *PB Guidance to the procurement tech on keeping track of tissues procured*

Exhibit C 11 *PB Guidance on procurement tech responsibility to obtain disease screening.*

Exhibit C 12 *PB Guidance to procurement tech regarding supplies for shipping to customers*

Exhibit C 13 *Supplies inventory that the PB provides for the procurement tech*

Exhibit C 14 *The compensation plan for the procurement tech*

Exhibit C 15 *Copy of the IRB document provided by the PB for the benefit of the customer*

Exhibit C 16 *Food and Drug Administration regulations on IRBs*

Exhibit C 17 *List of tasks performed by procurement tech*

V. ***Exhibit D1-3 Payments from the PB to Abortion Clinics for Fetal Tissue***

Exhibits D 1-3 *These documents show the monthly payments from the PB to several abortion clinics*

VI. ***Exhibit E 1-4 Payments from customers to the PB***

Exhibits E 1-4 *These document show payments from customers to the PB*

VII. ***Exhibit F Payments from a customer to the PB***

Exhibit F *This document shows annual payments from a single customer to the PB*

VIII. ***Exhibit G Reasonable Costs Associated with fetal tissue procurement***

Exhibit G *This graphic shows who bears the reasonable costs associated with fetal tissue procurement.*

IX. ***Exhibit H Rep. Waxman quote***

Exhibit H *This graphic is a quote from Rep. Waxman during the floor debate over H.R. 4.*

Exhibit A1

Understanding 42 USC § 289g-2

To profit under Title 42 USC § 289g-2, the transfer of any fetal tissue for valuable consideration must exceed the reasonable costs associated with the procurement.

The statute reads in part:

> § 289g-2(a): It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce.
>
> § 289g-2(e)(3): The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

Exhibit A2

Title 42 USC § 289g-2 requires that the transfer of fetal tissue not result in a profit.

Two Models

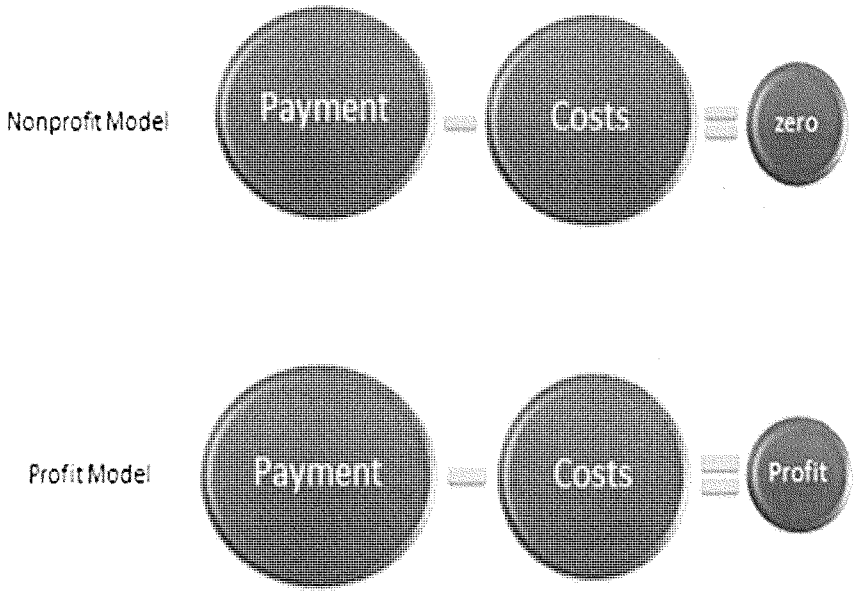


Exhibit B1

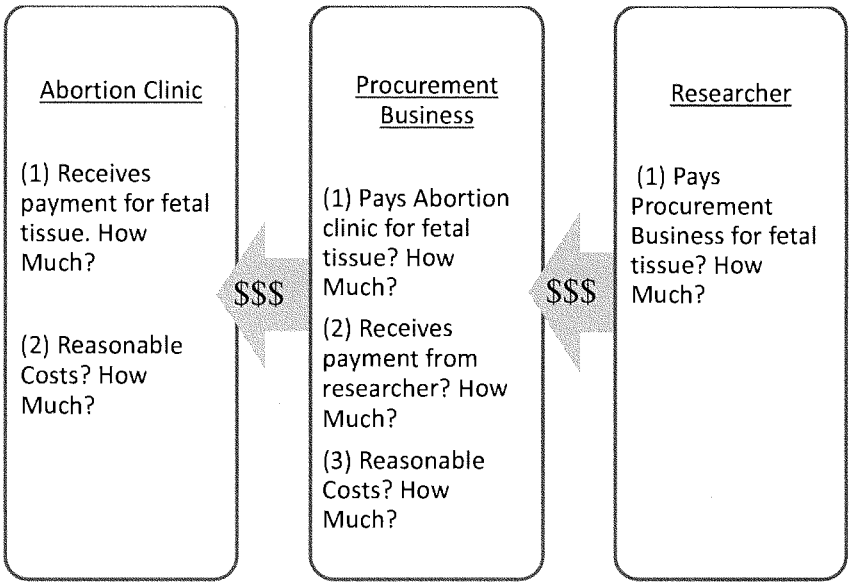
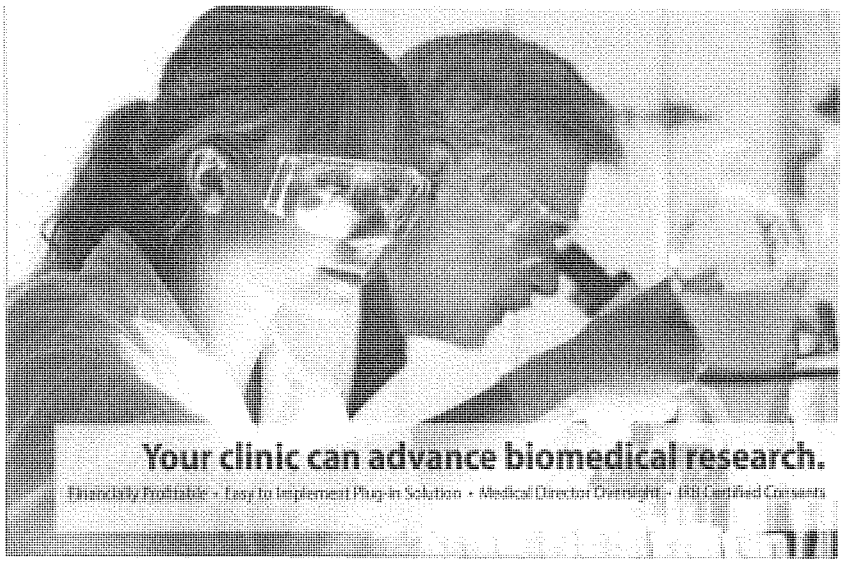

Abortion Clinic
(1) Receives payment for fetal tissue. How Much?
(2) Reasonable Costs? How Much?
$$$
Procurement Business
(1) Pays Abortion clinic for fetal tissue? How Much?
(2) Receives payment from researcher? How Much?
(3) Reasonable Costs? How Much?
$$$
Researcher
(1) Pays Procurement Business for fetal tissue? How Much?

Exhibit B2



Advancing BioMedical Research Together

Join the [redacted] partner program that fiscally rewards clinics for contributing to the advancement of life-saving research — with a solution that is easy to incorporate into your clinic practices. [redacted] is a California-based biomedical company that provides human tissue products ranging from fetal to adult tissues and healthy to diseased samples to many of the leading research institutions in the world. Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines.

Partnering with Obstetrical-Care Clinics

Cell-free fetal DNA circulates in maternal blood throughout pregnancy. Noninvasive, stem cell free methods to obtain fetal DNA are being used for earlier detection of genetic diseases as well as reproductive decision-making. Research pioneers who develop noninvasive diagnostic technologies rely on the blood samples that are collected from hospitals and clinics throughout the United States.

Easy to Implement Program + Financial Profits

[redacted] promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with [redacted], not only are you offering a way for your clients to participate in the unique opportunity to facilitate life-saving research, but you will also be contributing to the fiscal growth of your own clinic. The stem cell rich blood and raw materials that are usually discarded during obstetrical procedures can, instead, be expedited through [redacted] to research laboratories with complete professionalism and source anonymity.

Exhibit B3

Partnerships

Easy to Implement Program + Financial Profits

[redacted] promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with [redacted], not only are you offering a way for your clients to participate in the unique opportunity to facilitate life-saving research, but you will also be contributing to the fiscal growth of your own clinic. The stem cell rich blood and raw materials that are usually discarded during procedures can, instead, be expedited through [redacted] to research laboratories with complete professionalism and source anonymity.

Your Clinic can Advance Biomedical Research

- Financially Profitable
- Easy to Implement Plug-In Solutions
- Medical Director Oversight
- IRB Certified Consents

Partnering with Obstetrical-Care Clinics

Cell-free fetal DNA circulates in maternal blood throughout pregnancy. Noninvasive, stem cell free methods to obtain fetal DNA are being used for earlier detection of genetic diseases as well as reproductive decision-making. Research pioneers who develop noninvasive diagnostic technologies rely on the blood samples that are collected from hospitals and clinics throughout the United States.

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Exhibit B4

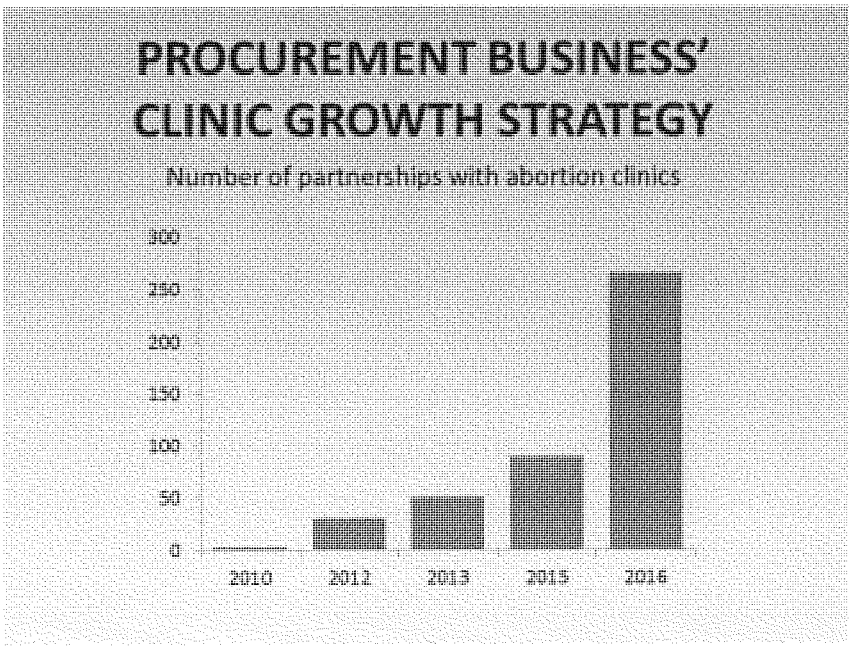


Exhibit B5

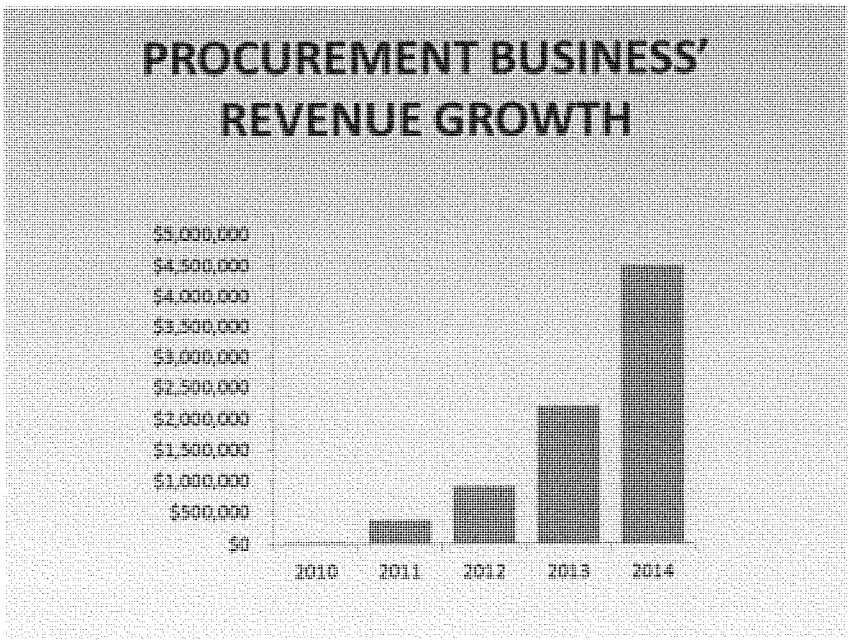


Exhibit B6

[Excerpt of a draft contract between the PB and the abortion trade association.]

PARTNERSHIP AGREEMENT

This Partnership Agreement (this "Agreement") is entered into as of March 25, 2015 ("Effective Date"). between [PB] . . . and the [abortion trade association] . . .

[The PB] agrees to make a donation to the [abortion trade association] in the amount of US $10,000 and undertake the activities listed in Appendix B . . .

[Abortion trade association's] Commitment

For the aforementioned sum mentioned in the section marked "Payment for Services," [the trade association] commits to performing the following for one year to assist [the PB] in presenting its collection program to [association] members:

- Create and disseminate to [association] members correspondence from [the association's] Group Purchasing Manager about [the PB] and the collection program twice yearly at the request of [the PB].
- Create a content section on [the association's] members-only website dedicated to [the PB], including a link to a [PB] email address for contacts and collection program information.
- Disseminate to [association] members the name and contact information of [the PB's] collection program representative who is available to answer questions about the [PB] collection program and participation on an ongoing basis.
- Provide a cover letter for [the association's] President and CEO pertaining to the [PB] collection program which [the PB] can use to accompany marketing materials for [association] members.
- Include a [PB] marketing brochure regarding [the PB's] collection program in each [association] membership welcome packet.
- Invite select [association] members to join [association] on a conference call paid for by the [PB] to discuss [the PB]'s collection program and the benefits of member participation at least once a year.
- Provide mailing list for [PB] to send out marketing materials to [association] members regarding the background of [the PB], its collection program, and benefits of member participation in the program.
- Provide assistance to [the PB] in gathering testimonials from existing program participants from among [association] members.
- Provide one complimentary exhibit space at [association's] Annual Meeting in the spring for [the PB] with up to 3 complimentary exhibitor registrations and up to 4 invitations to the member luncheons. In addition, the opportunity to create a bag insert that will be given to every attendee at registration.
- Supply [the PB] with a quarterly updated list of members.

Exhibit B6

APPENDIX B

[PB's] Commitment

[The PB] commits to performing the following for one year to market its collection services to [association] members:

- Conduct a webinar for [association] members with a question and answer forum discussing member participation in the [PB] collection program at the launch and yearly thereafter.
- Create and produce a marketing brochure detailing [the PB's] collection service program. This brochure shall include [PB] contact information. [The PB] will supply a copy of the brochure to [the association] to include in their membership welcome packets.
- Create and produce marketing "slicks" on the background of [the PB], its capabilities, and highlight participation benefits.
- Provide, at no charge to [the association], informative sessions or meetings that present the collection program.
- Develop client success stories on how [the PB] brought a value added service to participating members. This will help to inform members about [the PB's] offerings.
- Commit to attending [the association's] Annual Meeting in April of each year.
- Pursue all leads from [the association], introducing [the PB] and what [the PB's] capabilities are.

Exhibit C1

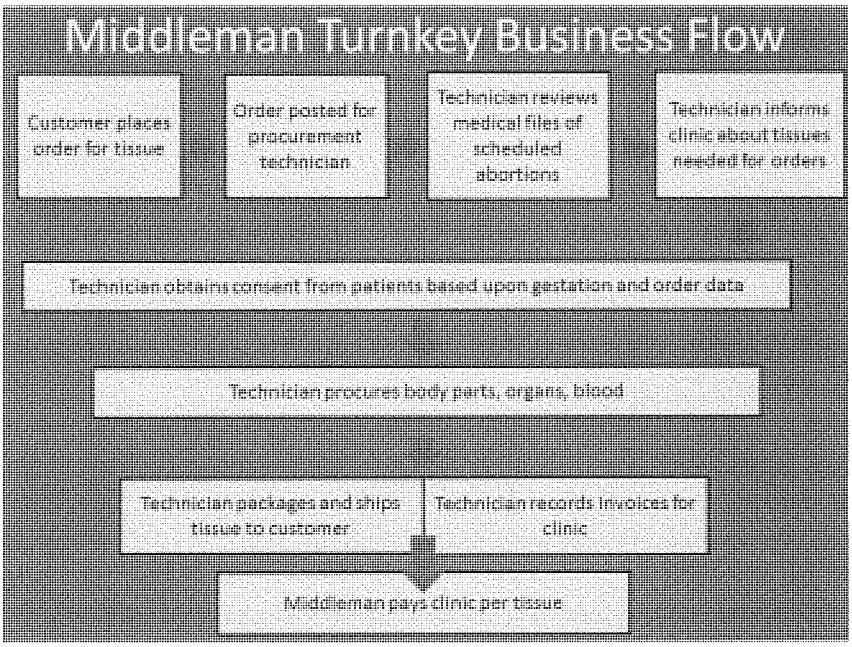

Middleman Turnkey Business Flow
Customer places order for tissue
Order posted for procurement technician
Technician reviews medical files of scheduled abortions
Technician informs clinic about tissues needed for orders
Technician obtains consent from patients based upon gestation and order data
Technician procures body parts, organs, blood
Technician packages and ships tissue to customer
Technician records invoices for clinic
Middleman pays clinic per tissue

Exhibit C2

WORKFLOW OF THE PROCUREMENT BUSINESS

1) Customer orders fetal tissue on-line. Exhibit C3.
2) Procurement business obtains Institutional Review Board approval. Exhibit C15.
3) Tissue technicians review the current researcher order list. Exhibit C4.
4) Tissue technicians discuss with the clinic the type of tissue being sought. Exhibit C9.
5) Review the schedule of abortions to match orders to gestational information and patient information. Exhibits C5, C7.
6) Tissue technicians obtain consent from women awaiting their procedure. Exhibit C8.
7) Procure blood and perform any tests on patients. Exhibits C6, C7, C10, C11.
8) Procurement business provides materials to tissue technicians. Exhibit C13.
9) Tissue technicians package and ship tissue to researcher using portable packaging materials. Exhibit C12.
10) Tissue technicians compensated per-tissue sample obtained. Exhibit C14.

Exhibit C3

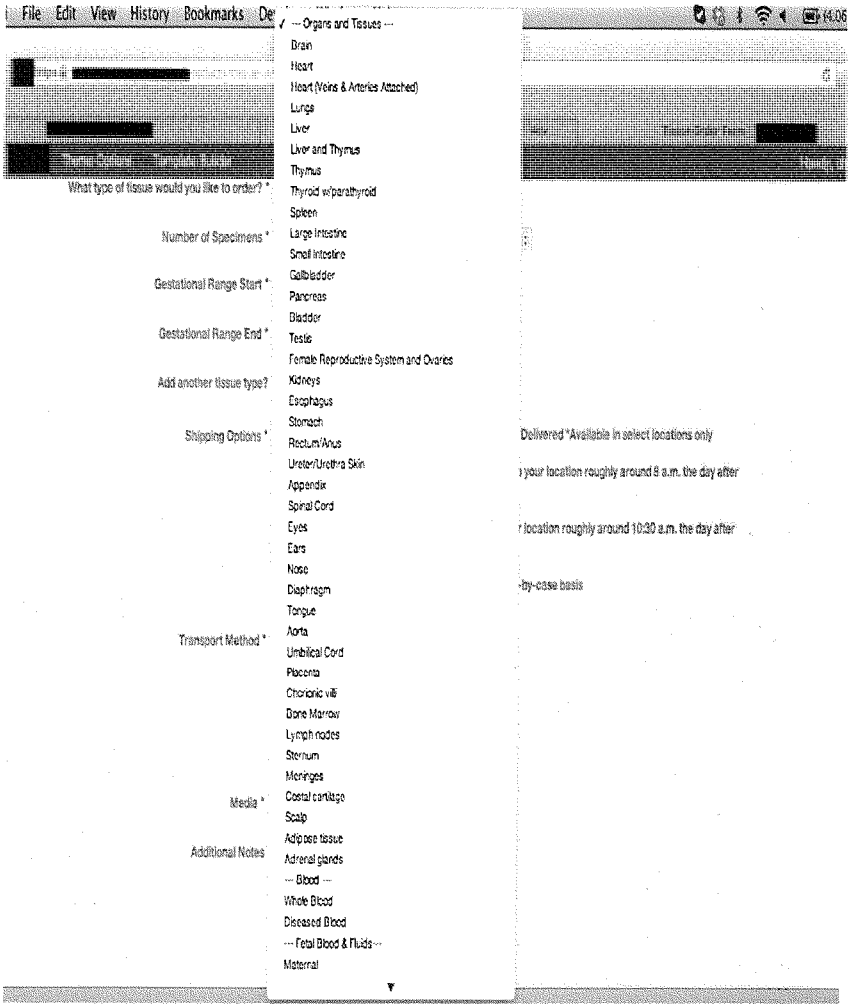

File Edit View History Bookmarks
What type of tissue would you like to order? *
Number of Specimens *
Gestational Range Start *
Gestational Range End *
Add another tissue type?
Shipping Options *
Transport Method *
Media *
Additional Notes
--- Organs and Tissues ---
Brain
Heart
Heart (Veins & Arteries Attached)
Lungs
Liver
Liver and Thymus
Thymus
Thyroid w/parathyroid
Spleen
Large Intestine
Small Intestine
Gallbladder
Pancreas
Bladder
Testis
Female Reproductive System and Ovaries
Kidneys
Esophagus
Stomach
Rectum/Anus
Ureter/Urethra Skin
Appendix
Spinal Cord
Eyes
Ears
Nose
Diaphragm
Tongue
Aorta
Umbilical Cord
Placenta
Chorionic villi
Bone Marrow
Lymph nodes
Sternum
Meninges
Costal cartilage
Scalp
Adipose tissue
Adrenal glands
--- Blood ---
Whole Blood
Diseased Blood
--- Fetal Blood & Fluids ---
Maternal
Delivered *Available in select locations only
your location roughly around 8 a.m. the day after
location roughly around 10:30 a.m. the day after
-by-case basis

Exhibit C4

From: [redacted]
Subject: Updated Task Assignment: Procurement Schedule Wednesday 3/20/13
Date: March 20, 2013 at 9:00 AM
To: [redacted]

The following task has been updated on the [redacted] web office site.

TASK NAME: Procurement Schedule Wednesday 3/20/13
ASSIGNED BY: [redacted]
PROJECT: Procurement Schedule
CATEGORY: Procurement Schedule
PRIORITY: 2-Normal
STATUS: 1-Not Started
ASSIGNED TO: [redacted]
VISIBLE TO: Everyone

DETAILS:
Liver & Thymus (same donor)/16-20wks/RPMI/Wet Ice/HIV,HBSAG,HCV,CMV/FedEx Priority Overnight/Mass General Hospital ([redacted])
1 SPEC=
IMPORTANT: Please document PO#0005446200 in the reference section

Liver & Thymus (Same donor)/16-20wks/RPMI /Wet Ice/ HIV,HBsAG,HCV/FedEx Priority Overnight/UMASS ([redacted])
1 SPEC=
IMPORTANT: Please document PO#0006147108 in the reference section.

Liver/18-22wks/RPMI/Wet Ice/FedEx Priority Overnight/ UCLA ([redacted])
IMPORTANT: Please document PO#1559NQA55800 in the reference section.
2 SPEC=
This used to be researcher- UCLA: [redacted]

Liver, Thymus & Skin (Same donor)/16-20wks/RPMI /Wet Ice/ HIV,HBsAG,HCV/FedEx Priority Overnight/HARVARD ([redacted])
1 SPEC=
IMPORTANT: Use FedEx account #431793989. Note: THE LIVER AND THYMUS SHIP TO [redacted] AT UMASS AND THE SKIN SHIPS TO [redacted] AT HARVARD. SHIP ALL TISSUE UNDER HARVARD'S FEDEX NUMBER.
** [redacted] Research Specialist Melton Group, HHMI/Harvard Dept of Stem Cell and Regenerative Biology, 7 Divinity Avenue-Fairchild 360, Cambridge, MA 02138, email- [redacted] Phone: [redacted]

PROCURE ON WEDNESDAY ONLY- Pancreas/14wks/HEPES with antibiotic/Gel Pack/HIV, HBSAG, HCV/FedEx Priority Overnight/UMASS ([redacted])
2 SPEC=
IMPORTANT: Use gel packs that are NOT frozen but just chilled.
IMPORTANT: Please document PO#0006147108 in the reference section.

Brain /16-18wks/Complete but can be in piecest/Use Client Supplied Media/Wet Ice/HIV,HBsAG,HCV/Use Clients FedEx Priority Overnight/Temple Univ ([redacted])

1 SPEC=
Note: Media contains anti-fungal/anti-mycotic and antibiotics
Researcher: [redacted]

Mid Brain/10+wks/RPMI/Wet Ice//HIV, HBSAG/FedEx Priority Overnight/University of Illinois at Chicago (Qu-Yang)
1 SPEC=
Researcher: [redacted] or [redacted]

Brain/14+wks (2cm in width)/Whole brain In-tact or one whole Hemis intact/Dry

Exhibit C5

[redacted]

Gestation Tracking Log

Name	Date			Location		
Number of Appointments Scheduled	<11.6wks	12-13.6wks	14-15.6wks	16-17.6wks	18-19.6wks	Total
Number of Appointments Kept	<11.6wks	12-13.6wks	14-15.6wks	16-17.6wks	18-19.6wks	Total
Number of Consents Signed	Blood			Tissue		
Number of Consent with Non Procurable Tissues – No Identifiable Organs*						
Number of Consents with Procurable Tissues but no Researcher*						

* High request organs such at Liver, Thymus, Pancreas, Heart

Exhibit C6

Maternal Blood Collection

There are 3 tubes in the [redacted] Procurement Kit 1: two 10ml EDTA and one 5ml Z serum sep. clot activator blood collection tube. All 3 tubes must be filled with maternal blood.

After the liver has been procured, use the items in the venipuncture collection kit, which will be either a leur-lok to collect from an existing IV or a needle and hub to collect the blood sample.

- Follow the clinic protocol for sterile blood collection.
- Fill the red 5ml Z serum sep. clot activator blood collection tube first and follow with the two 10ml EDTA tubes
- Once the blood is procured, all 3 tubes can go into the second biohazard bag.
- Seal the biohazard bag.

  - If a failed blood draw occurs, [redacted] can accept the liver tissue with a minimum of 2ml of maternal blood collected into the 5ml Z serum sep. clot activator blood collection tube. If the clinic is unable to procure any maternal blood for the tissue sample, [redacted] is unable to accept the tissue.

Filling out the Procurement Form

The sections of the Procurement Form that need to be filled out by the clinic are highlighted. The clinic is responsible for providing the following information:

- Date- date of procurement
- Time- time of procurement in military time
- Gest- gestation in weeks and days. For example: *18.3wks*
- Sex- sex of the fetus. *F* for female, *M* for male or *Unk* for unknown
- Donor age- age of the patient who consented to donate tissue and blood
- Height- in feet and inches. For example *5'3"*
- Weight- in pounds. For example *145 lbs*
- Ethnicity- ethnicity of the patient
- Smoker?- answer *yes* or *no*

Exhibit C7

[redacted]	**Work Instruction** [redacted] **Procurement Kit 1**	**Page 6 of 7**
		VERSION #: 1.0
Document Control Number [redacted]		**Effective Date: 12 May 2015**

[redacted]

Researcher Procurement Form

DATE 5/1/15

Delivery Instructions: ○ Billed/Recipient ○ Billed/[redacted]

Ship To:

Name	[redacted]	Email:	[redacted]
C/O		Email 2:	
Address		Email 3:	
Address 2		Phone #	
City		Cell Phone	
Country		Alt. Phone #	

FedEx Account [redacted] Tracking #

Ref# Local Delivery: ○ AM ○ PM Deliver By

Procurement Tech Additional Techs Location CFP-70

ID#	TIME	PATIENT#	SPEC#	GEST	SPECIMEN	SEX	COMMENTS
	14:00		6306	18.3wks	Liver	M	Donor age: 23 Height: 5'3" Weight: 145lbs Ethnicity: Hispanic Smoker? No
	14:15		31187B		Maternal Blood	F	2EDTA, 1 Z Serum Sep

Exhibit C8

Consenting Patients

It's important to connect with the patient, be compassionate as well as offering them an opportunity to make a difference in our future.

Blood and Tissue

I work with a company that assists researchers in finding cures for many debilitating diseases like cancer, diabetes and many other. The law in the state of California requires that the tissue from your procedure be incinerated. Would you be willing to give your consent to donate blood and the tissue from your procedure to research? Participation is completely anonymous.

Blood Only

I work with a company that assists researchers in finding cures for many debilitating diseases like cancer, diabetes and many other. Would you be willing to give your consent to donate a blood sample to research? Participation is completely anonymous.

Exhibit C8

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: [redacted]

Protocol Number: 101-01

Protocol Date: January 24, 2011

Principal Investigator: [redacted]

24-Hour Phone Number: [redacted]

Client Information for Informed Consent

DONATION OF ABORTED PREGNANCY TISSUE FOR MEDICAL RESEARCH, EDUCATION, OR TREATMENT

Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and many more. Tissue can be obtained as a result of donation of pregnancy tissue after an abortion. Before you give your consent to donate pregnancy tissue and/or a blood sample, read each of the following statements. If there is any statement you do not understand, or if you have any questions, someone will discuss them with you. Your participation is entirely voluntary.

Before this consent was ever offered to me, I had previously decided to have an abortion and signed an informed consent document.

I agree to donate the tissue from the abortion and/or miscarriage, and a blood sample if needed, as a bodily gift to be used for the advancement of medical science. I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed. The benefits of consenting to donation today include furthering medical research in finding cures for diseases like diabetes, leukemia, lymphoma, Parkinson's disease and more. The risks to this donation are minimal in that your abortion procedure will not change in any way; your health information will be protected at all times; and most blood donors have only minor discomfort from the needle stick, although some people may have a light-headed feeling, an upset stomach, bruising, or pain where the needle stick was. The alternative to this donation is to refuse consent.

Exhibit C8

I understand the donation is made without any restriction regarding who might receive the donated tissue or for what research purpose it might be used. I have not been informed of the identity of any individual who will receive the tissue that I am donating, and I understand that cells derived from the donation may be stored for years.

If you choose to participate, you will have your blood drawn by a trained phlebotomist or nurse. The amount is small, usually 10-60ml which is about 1-3 tablespoons. You will have no responsibilities once you leave the clinic.

In accordance with federal laws (HIPAA), your personal identifying information will be protected and not connected with your donation once the procedure is completed. Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your age, ethnicity, medical history, and number of previous pregnancies or abortions. All of this information will NOT be connected to your name or any other personal identifier.

Exhibit C8

CONSENT

You have the right to withdraw your donation at any time while in the clinic. Since your donation is completely ANONYMOUS, you cannot withdraw your donation once you leave the clinic as it will no longer be possible to know which donation was yours.

I understand there will be no payment to me for the donated tissue or for any product, process or service that may result from this donation.

I understand the method, timing or procedure of abortion cannot and will not be substantively altered for the purpose of obtaining the tissue. I understand that I may refuse to donate pregnancy tissue, and this will not affect my current medical care or my ability to get any future medical services at this clinic.

I understand that, if I have any questions about my donation, I can contact [redacted]

By signing below, I agree to donate tissue and/or blood as described above.

Signature:_____ Date:_____

Witness:_____ Date:_____

Exhibit C9

Clinic Procedures and Policies

As a representative of [redacted] you are required to act in a professional manner and follow all clinic policies. Please take note the following procedures and policies are **extremely important** regarding our presence in the clinics:

1. **Communication with the Assistant Manager and HSS's** – Upon arrival, inform the staff clearly what you are procuring for the day. Just as important, **you must inform the Assistant Manager and HSS's when you have completed your work.** This will insure they do not continue to consent and draw unnecessary blood samples. In addition, please **notify the Assistant Manager upon departure** of the clinic and remember to thank them for their assistance.

2. **Cell Phone Use** – It is essential we follow clinic rules with respect to cell phone use. **Please DO NOT pull your cell phones out in the hallways for ANY reason.** While we realize our cell phones are critical to our internal communication, we need to follow the etiquette set by the clinic. If you receive a text or call, step to an appropriate private area or into the nearest unoccupied room to read the text or answer your phone. Phones should always be on vibrate while in the clinics.

3. **Perfume Free Policy** – All clinics have a Perfume Free Policy, Please refrain from applying perfume or any fragrance prior to or when you are in the clinic.

4. **General Clinic Etiquette:**
   - Calm demeanor
   - Sensitive to Patients' Privacy and Situation
   - Professional at all Times
   - Respectful to Patients and Clinic Staff
   - Maintain Confidentially for Patient Information

[redacted]

Exhibit C10

Daily ID Numbering System

The Daily ID Numbering System allows us to track the number of bloods draws or tissue collections from a clinic. This is [redacted] Internal Tracking System, therefore it's important to number them properly and sequentially.

Blood Collection –

- ID Numbering for Blood Collections are always identified with a B on the end of the sequential number, i.e. 01B, 02B, 03B, etc.

- Start at 01B each day and sequentially number additional blood collections throughout the day, i.e. 01B, 02B, 03B, etc.

- IMPORTANT NOTE: We collect blood for multiple researchers. The ID# relates to the number of blood collections at the clinic NOT the researcher. For instance, let's say you draw the first 5 bloods for one researcher and then start getting bloods for another researcher, the first 5 bloods are 01B to 05B, then you would start numbering the second researcher at 06B. You would NOT start from 01B again. In addition, if you were alternating draws for different researchers, one may have 01B and 03B, and the other would be 02B and 04B.

Exhibit C11

Tissue Collection and Infectious Disease Screening (HIV, HBSAG, HCV, etc.) –

Tissue Collection:

- ID Numbering for Tissue Collections are identified as a sequential number, i.e. 01, 02, 03, etc. This relates to each case. For instance, if you procure multiple organs from a single case, they would all be identified as the same POC number.

- Start at 01 each day and sequentially number additional tissue collections throughout the day, i.e. 01, 02, 03, etc. Number only the cases you collect tissue.

Infectious Disease Screening (HIV, HBSAG, HCV, etc.):

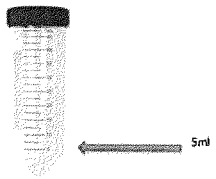
- ID Numbering for Infectious Disease Screening are identified as the same ID # in conjunction with the tissue it relates to. For instance, if you procure a tissue sample identified as ID #01 and the researcher requests Infectious Disease Screening on this patient, the blood test is the same ID #.

- IMPORTANT: Infectious Disease Screening relates to tissue collection only, therefore they are NOT identified with a B at the end of the ID number.

Packaging Tissue

After the liver is identified and separated from other tissue, place it in the 50ml conical tube provided in the kit.

- Separate the liver from the other fetal tissue. It can be in pieces or damaged but the combined volume must equal more than 5ml. The 5ml mark is clearly identifiable and visible on the conical tube.



- Remove and dispose of the parafilm from around the opening of the 50ml conical tube with the RPMI media.
- Place the liver tissue into the conical tube with the RPMI media and screw the top on tightly.
- Wrap the conical tube with parafilm to prevent any leakage.
  - Remove the paper backing from the parafilm.
  - Hold the parafilm down against the lid and with the other hand stretch the parafilm.
  - Stretch the parafilm around the lid of the conical tube in a clockwise direction.
  - Push the end of the parafilm into the conical tube to create a seal.
- Place the conical tube into a biohazard bag and seal the bag.

Assembling the kit for shipment

The items of the kit should be reassembled in the same placement as they were when the kit was received.

- Place the specimens inside of the plastic bag liner
  - One sealed biohazard bag with the 50ml conical tube (containing RPMI and the liver specimen)
  - One sealed biohazard bag with 3 tubes of maternal blood (two 10ml EDTA and one 5ml Z serum sep. clot activator blood collection tube)
  - 2 chilled gel packs
- Seal the plastic bag liner by tying it in a knot
- Place the tied plastic bag inside of the Styrofoam box
- Place the Styrofoam lid on the Styrofoam box
- Adhere a biohazard sticker on opposite sides of the Styrofoam box so they seal the top of the box to the bottom.
- Place Styrofoam box inside the cardboard box
- Place completed Procurement Form on top of the Styrofoam box
- Tape the cardboard box shut
- Adhere the FedEx shipping label to the top of the cardboard box

Once the package is ready for shipment call FedEx (1 800 GoFedEx or 1 800 463 3339) to schedule a pick up or drop the package off at the nearest FedEx location by 16:30 on the day of procurement.

Exhibit C13

[redacted]

Supply Inventory- North Clinic: by Supply Inventory (44 items)

Product	Volume Shipped	Quantity on Hand	Activity Type	Date Modified	Activity Notes	Modified By
Blood Tube (4 items)						
5ml Red Top Vacuettes for Marshall	50 per Flat	45	Supplies Received	Friday, January 11, 2013 2:40 PM PST	Received	[redacted]
ACD-A Tubes	100 per flat	100	Supplies Received	Friday, January 11, 2013 2:40 PM PST	ACD tubes received	
EDTA Tubes	100 per flat	0	Supplies Received	Friday, January 11, 2013 2:41 PM PST	EDTA tubes received	
Streck Tubes	100 per flat	39	Supplies Shipped	Wednesday, January 23, 2013 10:40 AM PST	sent 1 flat	
Phlebotomy Misc. (14 items)						
20 Gauge Needles	Box of 100	200	Supplies Received	Friday, January 11, 2013 2:42 PM PST	Needles received	
21 Gauge Needles	Box of 100	100	Supplies Received	Friday, January 11, 2013 2:43 PM PST	Needles received	
Alcohol Prep Pads	1 box	30	Supplies Received	Friday, January 18, 2013 8:22 AM PST	1 box received	
Band Aids	Box of 25	75	Supplies Received	Friday, January 11, 2013 2:43 PM PST	Bandaids received	
Bio Hazard Labels Rolls	Roll of 50	80	Supplies Received	Friday, January 11, 2013 2:47 PM PST	Supplies received	
Bio Hazard Ziploc Bags	Bag of 25	60 bags	Supplies Shipped	Monday, January 21, 2013 2:07 PM PST	sent 1 bag	
Blood Tube Packing Sleeves	Shipped as requested	22	Supplies Received	Friday, January 11, 2013 2:48 PM PST	Bags received	[redacted]
Cotton Balls	Bag of 100	100	Supplies Shipped	Monday, October 01, 2012 11:13 AM PST	Sent 1 ziploc bag of cotton balls	
Gel Ice Packs	Shipped as requested	9	Supplies Shipped	Tuesday, May 22, 2012 3:06 PM PST	sent via courier	
Needle Hubs w/ Safeties	Bag of 50	100	Supplies Received	Friday, January 18, 2013 8:22 AM PST	Received	
[redacted] Labels (Blood)	Roll of 200	120 labels	Supplies Shipped	Tuesday, April 24, 2012 9:58 AM PST	shipped via courier	
Surgical Tape(Micropore)	1 roll	2 roll	Supplies Shipped	Monday, January 21, 2013 2:07 PM PST	sent 1 roll	

Exhibit C13

Supply Inventory- North Clinic: by Supply Inventory [redacted]

Product	Volume Shipped	Quantity on Hand	Activity Type	Date Modified	Activity Notes	Modified By
Tourniquet	Shipped as requested	5				
Ziploc Bags (Regular)	Box of 54	50	Supplies Shipped	Tuesday, October 16, 2012 12:18 PM PST	sent 1 box ziploc	[redacted]
Shipping (11 items)						
Box Liners	Roll of 100	180	Supplies Shipped	Tuesday, April 24, 2012 9:59 AM PST	shipped via courier	
Bubble Wrap [redacted]	[redacted]mall roll	7 pouches	Supplies [redacted]equested	Thursday, January 24, 2013 9:22 AM PST	1 roll please	
Cardboard Only (Large)	Shipped as requested	8	Supplies Requested	Thursday, January 24, 2013 9:21 AM PST	3 please	
Cardboard Only (Small)	Shipped as requested	8	Supplies Requested	Thursday, January 24, 2013 9:21 AM PST	4 please	
FedEx Pouches	Bag of 25	18	Supplies Shipped	Tuesday, June 05, 2012 2:31 PM PST	shipped via courier	
Shipping Kit (Large)	Shipped as requested	0	Supplies Shipped	Tuesday, October 25, 2011 11:58 AM PST	10 large shipping kits sent via courier on 10/20/11	
Shipping Kit (Small)	Shipped as requested	0	Supplies Shipped	Tuesday, October 25, 2011 11:58 AM PST	10 small boxes sent via courier on 10/20/11.	
[redacted] Shipping Labels	Roll of 100	0	Supplies Shipped	Wednesday, February 15, 2012 12:09 PM PST	Supplies shipped via courier 2-15-12	
[redacted] Shipping Tape	0	0.5	Supplies Requested	Thursday, January 24, 2013 9:19 AM PST	1 roll please	[redacted]
Styrofoam Only (Large)	Shipped as requested	9	Supplies Requested	Thursday, January 24, 2013 9:20 AM PST	3 large styrofoams please	
Styrofoam Only (Small)	Shipped as requested	6	Supplies Requested	Thursday, January 24, 2013 9:20 AM PST	4 small styrofoams	
Special Projects - Researcher Provided Supplies (5 items)						
Ariosa Collection Kits	10	1				
Ariosa Preprinted Labels	20	10	Supplies Received	Friday, September 14, 2012 9:37 PM PST	1 set of 20 Ariosa pre-printed labels.	
Ariosa Shipping Kits	10	2				
Natera Collection Kits	10 kits	5 Kits	Supplies Received	Thursday, August 09, 2012 9:20 AM PST	39 Natera kits	
Sequenom Labels	Bag of 100	50	Supplies Received	Friday, January 18, 2013 8:27 AM PST	Labels received	[redacted]
Tissue Procurement (10 items)						

Exhibit C14

[redacted]

Procurement Technician Compensation Policy for Tissue and Blood Procurement Effective 01/01/2013

Procurement Fees

- Procurement Technicians are compensated at a rate of $10.00 per hour plus a per tissue or blood bonus as outlined in the table below:

Tissue Bonus Structure			
# Specimens	Category A*	Category B*	Category C
1-10 Specimens	$35/Tissue	$15/Tissue	$10/Blood
11-20 Specimens	$45/Tissue	$20/Tissue	$15/Blood
21-30 Specimens	$55/Tissue	$25/Tissue	$20/Blood
31-40 Specimens	$65/Tissue	$30/Tissue	$25/Blood
41-50 Specimens	$75/Tissue	$35/Tissue	$30/Blood

*Blood Samples may be obtained with these specimens in which case Category C bonus does not apply.

Please refer to the Procurable Specimens by Category dated 01/01/2013 for a detailed listing of Tissues.

Two or More Procurement Technicians working in Unison

- Procurement Technicians often work in unison so procurements are split equality between the technicians.

For example, if two technicians are working together at the same clinic, and two maternal bloods are procured, each technician would receive $5 for the Blood Procurement.

Exhibit C14

[redacted]

Procurable Specimens by Category
Effective 01/01/2013

Category A*
Brain
Heart
Lungs
Liver
Thymus
Thyroid w/parathyroid
Liver
Spleen
Large Intestine
Small Intestine
Gallbladder
Pancreas
Bladder
Testis
Ovaries
Esophagus
Stomach
Rectum/Anus
Ureter/Urethra
Appendix
Spinal Cord
Spinal Column
Eyes
Diaphragm
Lymph nodes
Sternum
Adipose tissue
Lymph nodes
All Muscle tissue
All Bone structures

Category B*
Kidneys
Adrenal glands
Ear
Decidua
Chorionic Villi
Umbilical Cord
Placenta
Amniotic Fluid
Large Intestine
Small Intestine
Skin
Nose
Tongue
Scalp

Category C
Maternal Blood
Post Surgery Blood
Umbilical Cord Blood
Trisomy Blood

*Note: Blood Samples may be obtained with these specimens in which case Category C bonus does not apply

[redacted]

Exhibit C15

BioMed·IRB

IRB Meeting Date: February 3, 2015 **Expiration Date:** February 5, 2016

BIOMED IRB CONTINUAL APPROVAL NOTIFICATION

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: [redacted]

Protocol Number: 101-01

Protocol Dates: January 24, 2011
Amendment # 1 dated January 24, 2011

Principal Investigator: [redacted]

Approved Facilities:

BioMed IRB has approved the above referenced study as having satisfied the criteria for continuing research at the February 3, 2015 meeting. This approval is effective from February 5, 2015.

The IRB committee has determined that the risk assessment for this study is Minimal. The IRB has determined that continuing review of this study will occur annually.

Approximately thirty days before February 5, 2016, you will be required to complete a Continuing Review Report Form. Continual review is the responsibility of the Principal Investigator. If you do not receive this form, please contact the IRB office immediately. The Continual Review Report Form must be received by the due date to allow ample time for ongoing review before the study's expiration date.

IRB approval is granted conditional on your adherence to the following requirements:

- The information submitted to the IRB is true and correct.
- Research will be conducted in accordance with the approved protocol.
- All materials used to recruit study subjects must be pre-approved by the IRB.
- Additional safeguards will be followed when vulnerable subjects, such as children or minors, are participants in the study.

The investigator agrees to report the following information to the IRB:

- Serious Adverse Events occurring at your site should be reported within ten (10) calendar days from the date of discovery by the investigator.
- Serious Adverse Events (IND Safety Reports) occurring at other sites should be reported no later

Exhibit C16

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL
PART 56 INSTITUTIONAL REVIEW BOARDS

Subpart D--Records and Reports
Sec. 56.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB as required by 56.108 (a) and (b).

(7) Statements of significant new findings provided to subjects, as required by 50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

Exhibit C17

January 3, 2011

Protocol Number: [redacted]

Protocol Date: January 24, 2011

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: [redacted]

Primary Investigator: [redacted]

Standard Operating Procedure

1. Purpose

This SOP covers Tissue Procurement for Non-therapeutic Research.

This protocol describes the set up, equipment and procedures for procuring cadaverous tissue to use in non-therapeutic research.

2. Scope

This applies to all procurements for non-therapeutic research.

3. Prerequisites

The day before surgery:
Check WebOffice for researcher requests;
Determine your location for the next day;
Call the clinic to verify how many surgeries are scheduled.

4. Responsibilities

It is the procurement technician's responsibility to bring the general and medical supplies listed in this SOP to each clinic. The clinic staff will identify donors. It is the procurement technician's responsibility to retrieve the tissue and package it appropriately for the given researcher. It is also the procurement technician's responsibility to update WebOffice so everyone is aware what tissue has been obtained and for whom.

5. Equipment

General supplies:
Current blank RPR (Researcher Procurement Record)
logs Pre-printed FedEx forms

[redacted]

Exhibit C17

General supplies:
Current blank RPR (Researcher Procurement Record) logs
Pre-printed FedEx forms

Medical supplies:
Scrubs
RPMI
Hepes Solution with antibiotic added
Petri dishes
Shipping boxes
Personal instruments to procure
Conical tubes
Mini urine specimen cups
Cold packs

6. Procedure

On the day of surgery, the following steps are taken to procure tissue from POC: Arrive at the clinic and change into scrubs.
Inform the consenting staff of which gestations to consent. Place chucks down.
Set up the light box, instruments, RPMI, Hepes, petri dishes and tubes or cups. Set up enough blood draw bags for the day.
Get out the sequential numbering labels.
Print a copy of the day's Procurement Schedule.
Follow along with the chart flow so you know what gestations to expect.
If required, initiate blood draw from clinic staff. We do NOT want a patient label on the blood tube. Give the clinic staff the blood bags and correct blood tubes for the given researcher. If these are blood samples to accompany the tissue sample, number them in order as soon as complete. See the SOP "Maternal Blood Samples for Infectious Disease Testing" for specific guidance on those blood samples.
Once a consenting donor has undergone surgery, procure the specimen(s) on the petri dish and light box.
With minimal manipulation after isolating the specimen(s), move the petri dish to the packaging room and carefully transfer the specimen(s) to the appropriate container (conical tube or mini urine specimen cup). Add the researchers media of choice and seal with parafilm.
Keep track of time, gestation, fetal foot size or sono report and date.
Package the specimens and blood tubing for shipment once all specimens have a number. Be sure to place them on ice or cold packs.
Note the specimen numbers on the RPR log. For delivery:
If the specimen is local courier, be sure to call the courier once you know you have obtained an appropriate specimen.
If the specimen is going by FedEx, be sure to know the local cut-off times for your closest FedEx office. Each FedEx location is listed under "contacts" in WebOffice. Always know which FedEx you will be dropping off at and consider traffic. Log on to www.fedex.com with your assigned log on and password. Print shipping label and affix to box.
All instruments must be sterilized once you are done for the day.
Clean the area(s) thoroughly and discard all unused POC in the appropriate receptacle. Gather your supplies to leave and change out of your scrubs.

Exhibit C17

7. Cautions

Health and Safety Warnings

All blood and tissue should be handled with standard Biohazard care. Gloves and other personal protective equipment should be worn at all times when handling blood or tissue. Meticulous care should be taken while using sharp dissecting instruments. Immediately report any injury to [redacted]

Interferences

Care should be taken to preserve the longevity of the equipment. This includes dissecting tools, light boxes, packaging supplies and media. Gentle handling of specimens is essential to quality control. Do not move or manipulate the tissue any more than is absolutely necessary. Ensure proper printer functioning first thing in the day, and contact [redacted] immediately if there are printer problems.

If you have an excellent sample with no researcher listed on today's schedule, please contact [redacted] immediately, and they will work to call researchers who may be interested even though they are not currently scheduled.

8. References

Researcher Procurement Record
MSDS for RPMI
MSDS for Hepes
MSDS for Antibiotic
SOP "Blood Samples for Infectious Disease"
HIPAA
Biohazard
Presentation

I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol; deviations from the protocol are acceptable only with a mutually agreed upon protocol amendment with the IRB approval. I also agree to report all information or data in accordance with the protocol, and in particular I agree to report serious adverse experiences as defined in this protocol.

[redacted]

Signature of Principal Investigator

3/17/2011

Date

[redacted]

Printed Name of Principal Investigator

Exhibit D1

[redacted]

[redacted]

9/5/12

Invoice Number: [redacted]
Please include the invoice number on all payments to [redacted]

For August 2012 sample collections.

Fresno (FL)
38 POCs x $55.00 = $2090.00
49 Bloods x $10.00 = $490.00

Fruitridge (FR)
0 POCs x $55.00 = 0
0 Bloods x $10.00 = 0

Mountain View (MV)
0 POCs x $55.00 = 0
0 Bloods x $10.00 = 0

N. Highlands (NH)
0 POCs x $55.00 = 0
0 Bloods x $10.00 = 0

Eastland Plaza (EP)
0 POCs x $55.00 = 0
4 Bloods x $10.00 = $40.00

Sacramento, "B" Street (BC)
68 POCs x $55.00 = $3740.00
80 Blood x $10.00 = $800.00

San Jose (SJ)
65 POCs x $55.00 = $3575.00
63 Bloods x $10.00 = $630.00

Seaside (SS)
0 POCs x $55.00 = 0
0 Bloods x $10.00 = 0

Stockton (NC)
0 POCs x $55.00 = 0
0 Bloods x $10.00 = 0

Total = $11,365.00

Please remit payment to:

[redacted]

UNITED

Exhibit D2

[redacted]

[redacted]

March 14, 2011

Invoice Number: [redacted]
Please include the invoice number on all payments to [redacted]

For January and February 2011 sample collections.

Stockton (NC)
1 POC's x $55.00 = $55.00
121 Bloods x $10.00 = $1210.00

Sacramento, "B" Street (BC)
27 POC's x $55.00 = $1485.00
327 Blood's x $10.00 = $3270.00

Fresno (FL)
12 POC's x $55.00 = $660.00
238 Bloods x $10.00 = $2380.00

Total = $9060.00

Please remit payment to:

[redacted]

Exhibit D3

[redacted]

[redacted]

February 17, 2014

Invoice Number: [redacted]

Please include the invoice number on all payments to [redacted]
Payments are due and payable within 30 days.

For January 2014 sample collections.

✓Fresno (FL)
1 POCs x $55.00 = $55
5 POC's x $35.00 = $175
68 Bloods x $10.00 = $680

Fruitridge (FR)
0 POCs x $55.00 = $0
0 Bloods x $10.00 =$0

✓Mountain View (MV)
2 POCs x $55.00 = $110
0 Bloods x $10.00 = $0

N. Highlands (NH)
0 POCs x $55.00 = $0
0 Bloods x $10.00 = $0

Eastland Plaza (EP)
0 POCs x $55.00 = $0
0 Bloods x $10.00 = $0

✓Sacramento, "B" Street (BC)
18 POCs x $55.00 = $990
0 POCs x $35.00 = $0
40 Bloods x $10.00 = $400

✓San Jose (SJ)
25 POCs x $55.00 = $1375
0 POCs x $35.00 = $0
74 Bloods x $10.00 = $740

✓Seaside (SS)
7 POCs x $55.00 = $385
0 POC x $35.00 = $0
8 Bloods x $10.00 = $80

✓Stockton (NC)
13 POCs x $55.00 = $715
1 POC x $35.00 = $35
27 Bloods x $10.00 = $270

Total = $6010.00

[redacted]

Exhibit E1

Redacted

PURCHASE ORDER

Redacted

Redacted

DATE	PURCHASE ORDER NO.
14-NOV-2014	60836838
PAGE NO.	REVISION NO.
Page 1 of 1	0

To:

United States
ATTN : Redacted

Ship To:

Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			19-NOV-2014	N30

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	S231 4 Human Fetal Brains As described in Invoice # S231	1	EACH	3,340.00	3,340.00

TAXABILITY	Authorized Signature	Direct questions to	ESTIMATED TAX:	292.25
Exempt because items are for resale. California Seller's Permit: Redacted	Redacted	Redacted	TOTAL:	3,632.25
Exempt as purchase on behalf of U.S. Government				
Exempt because use is exempted				

Chief Procurement Officer

Unless specifically stated otherwise, Redacted is subject to Sales Tax. Suppliers should invoice for taxable items. If a supplier does not have the authority to collect California Sales Tax, Redacted will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 18662, requires withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference http://www.ftb.ca.gov/

Exhibit E2

Redacted

PURCHASE ORDER

DATE	PURCHASE ORDER NO.
25-SEP-2014	60762875
PAGE NO.	REVISION NO.
Page 1 of 1	0

To:

United States
ATTN : Redacted

Ship To: Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			27-SEP-2014	N30

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	#YT0101F Human Fetal Tissue: Gestation requirements: 12-20 weeks	10	EACH	595.00	5,950.00
2	#PKG0100 Packaging- Gel Pack or Wet Ice	10	EACH	15.00	150.00
3	#SD00103 Local Delivery Flat Rate - 101 to 150 miles	10	EACH	225.00	2,250.00

TAXABILITY

Exempt because items are for resale. California Sellers Permit: Redacted

Exempt as purchase on behalf of U.S. Government

Exempt because use is exempted.

Authorized Signature: Redacted

Chief Procurement Officer

Direct questions to: Redacted

ESTIMATED TAX: 730.64

TOTAL: 9,000.64

Unless specifically stated otherwise, Redacted is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, Redacted will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 18662, require withholding for payments made to nonresidents of California for income earned in California related to independant contractor services, rent, and royalty distributions. For more information on this requirement reference https://www.ftb.ca.gov/forms/2012/12_1017.pdf.

Exhibit E3

Redacted

PURCHASE ORDER

DATE	PURCHASE ORDER NO.
09-FEB-2015	60891260
PAGE NO.	REVISION NO.
Page 1 of 1	0

To:

United States
ATTN : Redacted

Ship To:

Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			09-FEB-2015	N30

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	FT0101F Human Fetal Tissue (Estimate 5251) - Gestation requirements: 18-19 weeks - - upper and lower limbs with hands and feet	1	EACH	890.00	890.00
2	FT0101F Human Fetal Tissue (Estimate 5251) - Calvarium - Matched to upper and lower limbs	1	EACH	595.00	595.00

TAXABILITY

Exempt because items are for resale. California Sellers Permit: Redacted

Exempt as purchase on behalf of U.S. Government

Exempt because use is exempted

Authorized Signature: Redacted

Chief Procurement Officer

Direct questions to: Redacted

ESTIMATED TAX: 129.95

TOTAL: 1,614.95

Unless specifically stated otherwise, Redacted is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, Redacted will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 18662, require withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference https://www.ftb.ca.gov/forms/2012/12_1017.pdf.

Exhibit E4

Okay to Pay Invoice [redacted]

[redacted]

Initiator [redacted]

Invoice

Date	Invoice #
01/19/2012	1439
Terms	Due Date
Due on receipt	01/19/2012

Bill To

[redacted]

Purpose: the tissues are used for RNA extraction to perform genome-wide gene expression of brains exposed to environmental stressors

Ship Via	Researcher	Shipping
FedEx	[redacted]	[redacted]

Description	Qty	Price	Amount Due
01/14/2012			
• Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 04, 05	4:00	715.00	2,860.00
• Fedex Priority Overnight	1:00	85.00	85.00
Subtotal: 01/14/2012 = $2,945.00			
01/17/2012			
• Fedex Priority Overnight	1:00	85.00	85.00
• Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 03	3:00	715.00	2,145.00
Subtotal: 01/17/2012 = $2,230.00			
01/19/2012			
• Credit for 1/14/12 Samples - Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 04, 05	-4	715.00	-2,860.00
• Credit for 1/14/12 - Fedex Priority Overnight	-1	85.00	-85.00
Subtotal: 01/19/2012 = $ -2,945.00			
[redacted]		Total	$2,230.00

X [redacted] Administrator [redacted] 01/27/2012

Exhibit F

Fetal Tissue Sales by Client Detail

January - December 2014

Customer Name	Date	Transaction Type	Invoice Number	Product/Service	Memo/Description	Qty	Rate	Amount
[redacted]								
	01/10/2014	Invoice	3253	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	01/14/2014	Invoice	3254	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	01/17/2014	Invoice	3255	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	01/23/2014	Invoice	3256	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	02/06/2014	Invoice	3441	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	02/13/2014	Invoice	3442	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	02/19/2014	Invoice	3515	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	3.00	595.00	1,785.00
	02/20/2014	Invoice	3569	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	02/21/2014	Invoice	3570	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	02/27/2014	Invoice	3603	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	03/06/2014	Invoice	3719	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	03/14/2014	Invoice	3738	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	03/19/2014	Invoice	3773	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	03/21/2014	Invoice	3795	FT0101F	Item #FT0101F: Human Fetal Tissue - Upper/Lower Limbs	1.00	890.00	890.00
	03/21/2014	Invoice	3797	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	04/03/2014	Invoice	3876	FT0101F	Item #FT0101F: Human Fetal Tissue - Upper/Lower Limbs	1.00	890.00	890.00
	04/04/2014	Invoice	3885	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	04/11/2014	Invoice	3907	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	04/18/2014	Invoice	3978	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	04/25/2014	Invoice	4023	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	05/02/2014	Invoice	4065	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	05/09/2014	Invoice	4119	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	05/16/2014	Invoice	4171	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	2.00	595.00	1,190.00
	05/23/2014	Invoice	4214	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	06/10/2014	Invoice	4323	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	06/17/2014	Invoice	4369	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	06/18/2014	Invoice	4428	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	07/02/2014	Invoice	4449	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	07/10/2014	Invoice	4529	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	07/10/2014	Invoice	4529	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	07/17/2014	Invoice	4544	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	07/22/2014	Invoice	4583	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	07/22/2014	Invoice	4584	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	07/31/2014	Invoice	4656	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	2.00	595.00	1,190.00
	07/31/2014	Invoice	4639	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	08/05/2014	Invoice	4681	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	08/05/2014	Invoice	4681	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	08/13/2014	Invoice	4753	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	08/13/2014	Invoice	4752	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	08/13/2014	Invoice	4728	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	08/14/2014	Invoice	4783	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	08/14/2014	Invoice	4761	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	08/19/2014	Invoice	4799	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	08/19/2014	Invoice	4802	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	08/27/2014	Invoice	4844	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	09/02/2014	Invoice	4882	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	09/11/2014	Invoice	4934	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	09/18/2014	Invoice	4990	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	09/19/2014	Invoice	4992	FT0101F	Item #FT0101F: Human Fetal Tissue - Heart	1.00	595.00	595.00
	09/19/2014	Invoice	4993	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	09/19/2014	Invoice	4994	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	09/23/2014	Invoice	5013	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	09/23/2014	Invoice	5012	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	09/30/2014	Invoice	5037	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	10/01/2014	Invoice	5055	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	10/09/2014	Invoice	5104	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	10/15/2014	Invoice	5111	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	10/21/2014	Invoice	5137	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	10/21/2014	Invoice	5136	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	11/12/2014	Invoice	5278	FT0101F	Item #FT0101F: Human Fetal Tissue - Liver	1.00	595.00	595.00
	11/12/2014	Invoice	5279	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	11/18/2014	Invoice	5321	FT0101F	Item #FT0101F: Human Fetal Tissue - Pancreas	1.00	595.00	595.00
	11/20/2014	Invoice	5345	FT0101F	Item #FT0101F: Human Fetal Tissue - Fetal Upper/Lower Limbs	1.00	890.00	890.00
	12/02/2014	Invoice	5392	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	12/03/2014	Invoice	5398	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
	12/10/2014	Invoice	5431	FT0101F	Item #FT0101F: Human Fetal Tissue - Brain	1.00	595.00	595.00
Total for [redacted]								$ 42,535.00
[redacted]								

Exhibit G

Who Bears the Reasonable Cost of Tissue Procurement?

Abortion Clinic	Procurement Business	Customer
	Tissue Tech Salary	Shipping of Tissue
	Bonus to Tissue Tech	Supplies for Tissue Procurement
	Payment to AC for Tissue	Payment to PB for Tissue
	Consent to Obtain Tissue	Infectious Disease Screening
	Tissue Procurement	
	Blood Procurement	

Explanation: The AC has no costs so the payments from the PB to the AC are pure profit. All costs are born by the PB or the Customer. The payments from the Customer to the PB exceed its cost by a factor of 300 to 400 percent.

Exhibit P

REP. HENRY WAXMAN ON THE SALE OF FETAL TISSUE

"This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any purpose, just not for the purpose of research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale."

-139 Cong. Rec. H1131 (Mar. 10, 1993)

Source of Exhibits

Exhibit A1 – Rule of Law
Source: Title 42 USC §289 g-2(a)

Exhibit A2 – Graphic: Two Business Models
Source: Staff-created document based on Title 42 USC §289 g-2(a)

Exhibits B1 – Business Model of the Middleman Procurement Business
Source: Staff-created chart based on procurement business, abortion clinic, customer documents

Exhibit B2 – Company brochure used to market the PB to Abortion Clinics
Source: National abortion organization

Exhibit B3 – Company website used to market the PB to Abortion Clinics
Source: Procurement business

Exhibit B4 – Chart showing growth of the PB in number of Abortion Clinics
Source: Staff-created document based on sworn statements of PB owner, and contract with abortion organization

Exhibit B5 – Chart showing growth of PB revenue
Source: Congressional Research Service

Exhibit B6 – Contract between the PB and a national abortion organization to acquire an additional 400 clinics
Source: National abortion organization

Exhibit C1 – Daily work flow of the PB procurement tech procuring fetal tissue inside Abortion Clinics
Source: Staff-created chart based on procurement business

Exhibit C2 – List of the tasks performed by the PB procurement tech inside the Abortion Clinics
Source: Procurement business

Exhibit C3 – Web site screen grab of how to order fetal tissue
Source: Procurement business

Exhibit C4 – Website and phone orders sent to procurement techs inside abortion clinics
Source: Procurement business

Exhibit C5 – Form the procurement tech uses to check gestation periods so that patients can be matched with orders.
Source: Procurement business

Exhibit C6 – Work instructions on procurement given to the procurement tech by the PB for work performed inside the abortion clinic.
Source: Procurement business

Exhibit C7 – Procurement Kit provided by the PB
Source: Procurement business

Exhibit C8 – PB guidance on obtaining patient consent by procurement tech
Source: Procurement business

Exhibit C9 – PB directs tissue tech to tell the abortion clinic manager what is being procured that day.
Source: Procurement business

Exhibit C10 – PB Guidance to the procurement tech on keeping track of tissues procured
Source: Procurement business

Exhibit C11 – PB Guidance on procurement tech responsibility to obtain disease screening
Source: Procurement business

Exhibit C12 – PB Guidance to procurement tech regarding supplies for shipping to customers
Source: Procurement business

Exhibit C13 – Supplies inventory that the PB provides for the procurement tech
Source: Procurement business

Exhibit C14 – The compensation plan for the procurement tech
Source: Procurement business

Exhibit C15 – Copy of the IRB document provided by the PB for the benefit of the customer
Source: Procurement business

Exhibit C16 – Food and Drug Administration regulations on IRBs
Source: Code of Federal Regulations

Exhibit C17 – List of tasks performed by procurement tech
Source: Procurement business

Exhibit D1-3 – Monthly payments from the PB to several abortion clinics
Source: Procurement business

Exhibit E1-4 – These document shows payments customers to the PB
Source: Procurement business

Exhibit F – This graphic shows who bears the reasonable costs associated with fetal tissue procurement
Source: Staff-created chart based on procurement business, abortion clinic, customer documents

Exhibit G – Chart showing who bears the reasonable cost of tissue procurement
Source: Staff-created chart based on procurement business, abortion clinic, customer documents

Exhibit H – Rep. Waxman quote
Source: Congressional Record

HEARING ON THE *PRICING OF FETAL TISSUE*

Background

Congress Passed H. Res. 461

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Panel on Infant Lives and empowered the panel to investigate issues including "Federal funding and support of abortion providers," as well as all "relevant matters with respect to fetal tissue procurement." The Panel Chairman, Congressman Marsha Blackburn, has scheduled a hearing to explore information about the pricing of the tissue and whether abortion clinics and middleman businesses were making a profit from the transfer of fetal tissue.

The release of videos last summer raised the question of whether abortion clinics and middleman tissue procurement businesses were profiting from the sale of baby body parts, organs and tissues. To profit from the acquisition or transfer of fetal tissue violates Title 42 USC §289 g-2, which prohibits the transfer of any fetal tissue for valuable consideration that exceeds the reasonable costs associated with the procurement.

History of the Prohibition of Profiting from Fetal Tissue Sales

On March 10, 1993, the House debated two competing amendments to H. R. 4 the National Institutes of Health Revitalization Act of 1993. Amendments, one offered by Mr. Bliley and one by Mr. Waxman focused on safeguards for the donation of fetal tissue for transplantation and for research. The House passed the Waxman Amendment to H.R. 4, the National Institutes of Health Revitalization Act of 1993. That Amendment includes the provisions codified as 42 USC 289 g-2(a) and (e)3:

> **42 USC §289 g-2(a) states "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."**
>
> **42 USC §289 g-2(e)(3) "The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."**

During Floor debate it was repeated over and over by supporters of the Waxman Amendment that fetal "tissue may not be sold."[1] Mrs. Morella expressed her support for the legislation because "fetal tissue could not be sold."[2] Mr. Waxman himself said:

> This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any

[1] 139 Cong. Rec. 1099 (1993) (statement of Rep. John Edward Porter in support of the Waxman Amendment).
[2] Id. (statement of Rep. Connie Morella in support of HR 4 and the Waxman Amendment).

> purpose, just not for the purpose of research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.[3]

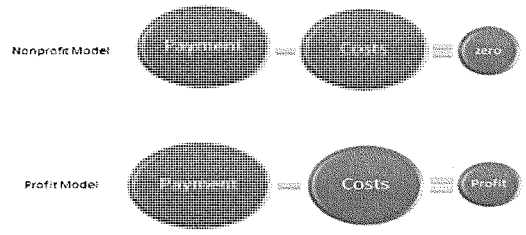
The floor debate corroborates Committee Report language. The Report of the National Institutes of Health Revitalization Act of 1993 from the Committee on Energy and Commerce stated:

> Section 498B prohibits the purchase of human fetal tissue as well as the solicitation or acceptance of directed fetal tissue donations.[4]

The Committee prohibition on the sale of fetal tissue is described as making the transfer of fetal tissue parallel with donation of other organs under the Organ Procurement and Transplantation Act.[5] But the Committee Report adds, "Indeed the Committee has dealt with fetal tissue more restrictively . . . ."[6] The Committee intent is to disallow payment for procurement of any organs.

The intent of the statute is best understood through a simple contrast between two modes of transferring fetal tissue from one entity to another. With the first, an abortion clinic (AC) or middleman Procurement Business (PB) transfers tissue to a researcher, and the researcher may reimburse the AC or PB for its reasonable costs incurred by the transportation, processing, preservation, and quality control of the tissue. With the second, the payment from the researcher exceeds those reasonable costs, enabling the AC or PB to make a profit and thus violates the statute.

This is graphically explained below:



The factual scenario presented by the Select Panel on April 20, 2016, will focus on a particular *Procurement Business* that offers fetal tissue for sale to researchers through a website procurement page or through phone orders. The *Procurement Business* assigns its employees to

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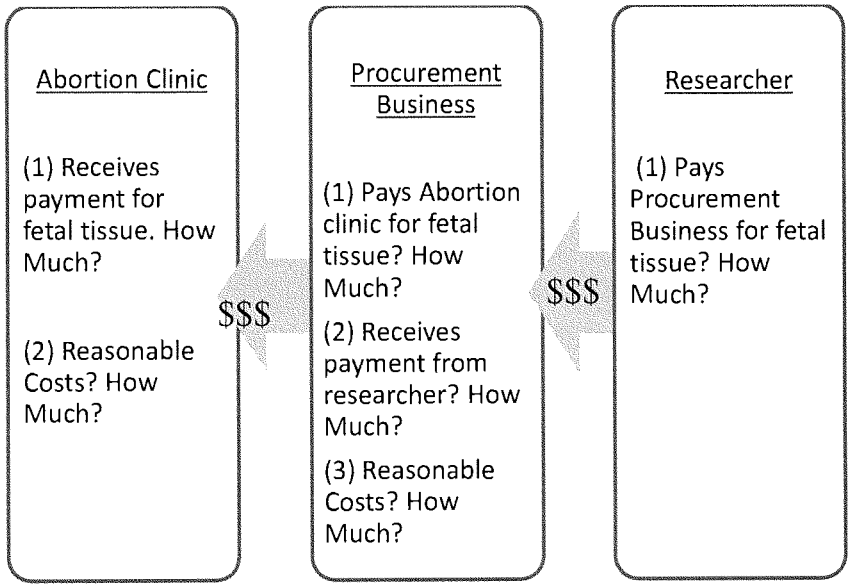
[3] Id. (statement of Rep. Henry Waxman).
[4] H.R. Rep. No. 103-28 at 76 (1993).
[5] Pub. L. No. 98-507, 98 Stat, 2339 (1984).
[6] H.R. Rep. No. 103-28 at 76 (1993).

a group of abortion clinics to procure fetal tissue and then ships the tissue to customers. The *Procurement Business* pays the abortion clinics a fee *per item of tissue* that its employees procure. The next graphic shows the transfer of payments and raises the question of, "How much are the reasonable costs that would offset the payments?"

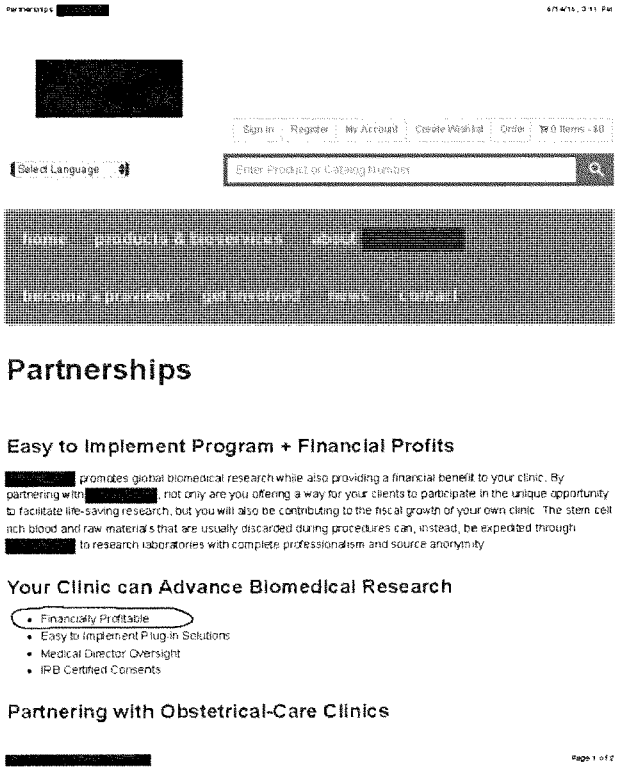


If the payments from the *Procurement Business* to the Abortion Clinic exceed the reasonable costs incurred by the clinic, then the Abortion Clinic has a profit and violates the statute. If the payments from the researcher/customer exceed the reasonable costs incurred by the *Procurement Business*, then the *Procurement Business* has a profit and violates the statute.

How the Procurement Business Markets its Product

Both the *Procurement Business* company brochure and its website marketed itself to abortion clinics as a way to improve the profitability of the abortion clinic. Below are graphic samples of these materials. The company brochure was distributed at a national abortion trade association conference.

Exhibit B3



Partnerships [redacted] 6/14/15, 3:11 PM

[redacted]

Sign In | Register | My Account | Create Wishlist | Order | 0 Items - $0

Select Language

Enter Product or Catalog Number

[redacted]

Partnerships

Easy to Implement Program + Financial Profits

[redacted] promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with [redacted], not only are you offering a way for your clients to participate in the unique opportunity to facilitate life-saving research, but you will also be contributing to the fiscal growth of your own clinic. The stem cell rich blood and raw materials that are usually discarded during procedures can, instead, be expedited through [redacted] to research laboratories with complete professionalism and source anonymity.

Your Clinic can Advance Biomedical Research

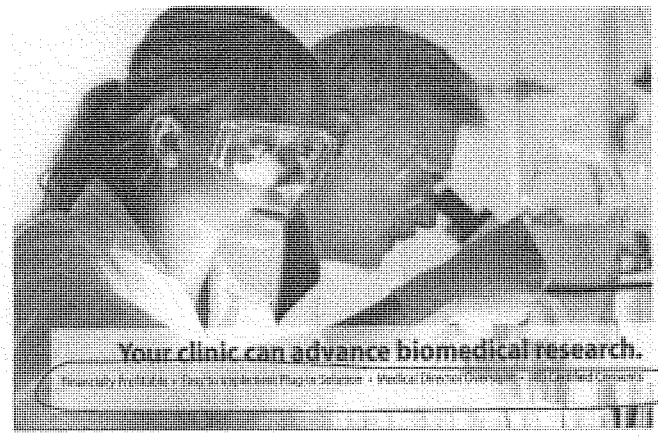
- Financially Profitable
- Easy to Implement Plug-in Solutions
- Medical Director Oversight
- IRB Certified Consents

Partnering with Obstetrical-Care Clinics

[redacted]

Page 1 of 2

Exhibit B2



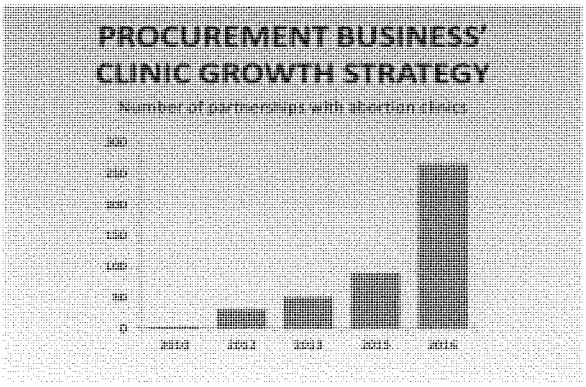
[redacted] is a California-based biomedical company that provides qualified research laboratories with human cells, fluids, blood and tissue products for the pursuit of disease detection and cure. We procure, preserve, isolate and deliver cell lines exclusively to research facilities across the world. [redacted] products are not available for patient care. [redacted] is accredited by an independent biomedical Institutional Review Board.

"Our partnership with [redacted] is beneficial in a number of ways. First, it allows us to contribute to lifesaving research that is advancing diagnostic and medical care. Second, [redacted] has a Plug-In Solution that allows us to add additional clinics quickly. Lastly, I feel confident that our patient's anonymity is secure through their strict protocols and practices."
– Dr. Dorothy Torgerson, Planned Parenthood Mar Monte

The *Procurement Business* Abortion Clinic Acquisition

From its inception in 2010, the *Procurement Business* was very successful at acquiring new abortion clinics from which to procure fetal tissue. In a business magazine article and in sworn legal documents, the *Procurement Business* CEO explained that the business started out in 2010 with three clinics and within two years had 30 clinics. The next milestone was achieved in 2015 when the *Procurement Business* had nearly 100 abortion clinics. During 2014 and 2015 the *Procurement Business* sought a co-marketing relationship with a national abortion clinic trade association. The contract, if ratified, would have given the *Procurement Business* over 250 abortion clinics from which to procure fetal tissue for resale. The contract was never ratified due to several factors, including the public release of the videotapes in 2015. The graph below shows the dramatic growth in the number of abortion clinics.

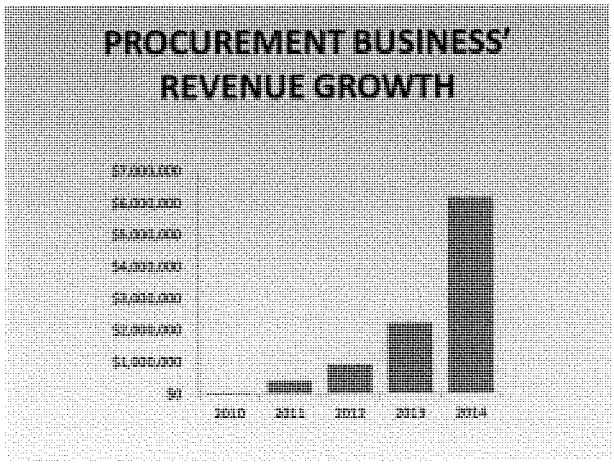
Exhibit B4



Revenue Growth

Along with the growth in the number of abortion clinics, the *Procurement Business* experienced significant growth in income. The company was featured is several business articles and was listed as one of the fastest growing companies in the nation.

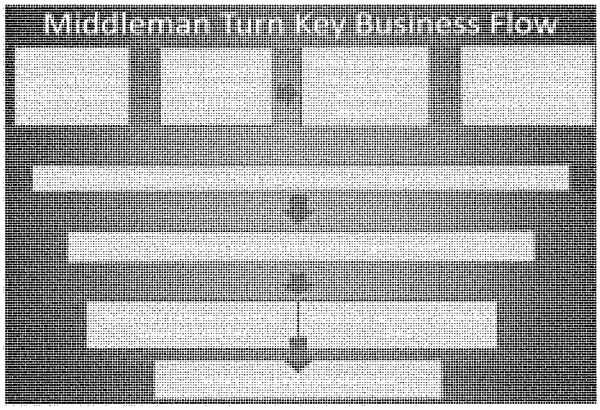
Exhibit B5



The *Procurement Business* offers a Turnkey or Plug in Service for Abortion Clinics

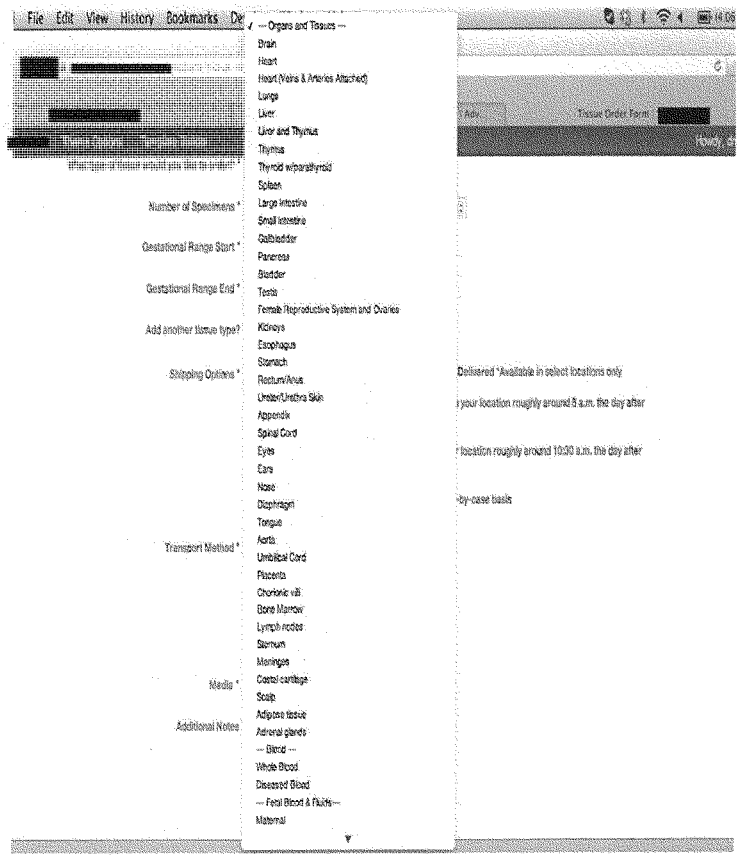
The *Procurement Business* marketed itself as a way for clinics to make additional income by allowing the *Procurement Business* procurement technicians to take fetal tissues and organs from aborted babies immediately after the abortion was completed. The Select Panel investigation reveals that every conceivable task is performed by the Procurement business employees that are assigned to one or more clinics. The first step in the process is for the researcher to make an online order. The screen grab below shows the view that the researcher or customer would have when ordering. After selecting particular baby parts, the next step would be to select the gestational period and finally the method of shipment.

Exhibit C1



The Chart below is a website screen grab of the Procurement Business order form for fetal organs.

Exhibit C3



Daily Tasks Performed by the Procurement Tech

The **work day of the procurement tech** is best understood by a review of the "C" Exhibits in particular C16 (included in the Appendix).

1) First thing in the morning the tissue tech gets an email like the one at C4. She reads the orders for certain baby body parts and the gestation period. Now she knows what she needs to harvest that day.
2) Then she checks in with the Abortion Clinic Assistant Manager and informs the staff what she will be procuring that day. Described at C9.
3) Then the procurement tech reviews the private medical files of the patients for that day to learn their names and the gestation time of their baby. She records the gestations on the gestation tracking log at C5.
4) Next the procurement tech approaches the patients waiting to be prepped for their abortion. She doesn't have much time so she must match her orders for the day with patients who are at the right gestation time. She asks for the patients by name. Then she convinces them to consent to donate saying that her donation is all about cures of Diabetes and Parkinson's and Heart Disease. Exhibit C8.
5) After the abortion the procurement tech collects the baby's remains and procures the body parts she needs. She carries all of her supplies with her. Described at Exhibit C13. Her shipping supplies are described at Exhibit C12.
6) The tissue tech then arranges for delivery: a courier, Fed EX.
7) She gets an hourly wage and a bonus for each tissue.

The Exhibit "C" group of documents taken as a whole represents the comprehensive role and tasks undertaken by the *Procurement Business* employee, the procurement technician. Understanding these documents as a group is critical to the analysis of whether the abortion clinics had any responsibility or tasks at all related to the fetal tissue. In fact, it is hard to conceive of the abortion clinics doing anything at all other than being paid per tissue for the work performed by the *Procurement Business*.

The "C" documents show, in great detail, that all possible management guidance, tasks, and responsibilities are undertaken by the PB procurement tech employee and that that no tasks are performed by the abortion clinic. Thus, the costs of tissue acquisition are entirely born by entities other that the abortion clinic.

Exhibit C1 *This is the daily work flow of the PB procurement tech procuring fetal tissue inside Abortion Clinics*

Exhibit C 2 *This is a list of the tasks performed by the PB procurement Tech inside the Abortion Clinics*

Exhibit C 3 *Web site screen grab of how to order any fetal tissue you want*

Exhibit C 4 *Website and phone orders sent to procurement tech via email inside abortion clinics*

Exhibit C 5 *Form the procurement tech uses to check gestation periods so that patients can be matched with orders.*

Exhibit C 6 *Work instructions on procurement given to the procurement tech by the PB for work performed inside the abortion clinic.*

Exhibit C 7 *Procurement Kit provided by the PB*

Exhibit C 8 *PB guidance on obtaining patient consent by procurement tech*

Exhibit C 9 *PB directs tissue tech to tell the abortion clinic manager what is being procured that day.*

Exhibit C 10 *PB Guidance to the procurement tech on keeping track of tissues procured*

Exhibit C 11 *PB Guidance on procurement tech responsibility to obtain disease screening*

Exhibit C 12 PB *Guidance to procurement tech regarding supplies for shipping to customers*

Exhibit C 13 *Supplies inventory that the PB provides for the procurement tech*

Exhibit C 14 *Copy of compensation plan for the procurement tech*

Exhibit C 15 *Copy of the IRB documents provided by the PB for the benefit of the customer*

Payments from Procurement Business to Abortion Clinic (includes blood)

The chart below summarized the flow of payments between the entities described above. The full exhibits are included in the Appendix.

D Exhibits

August 2010 ..... $11,365

Jan/Feb 2011 ..... $ 9,060

January 2014 ..... $ 6,010

Payments from Researcher/Customer to Procurement Business

E Exhibits

Fetal Brains-1 each $3,340

Human Fetal Tissue 10@595.00 each $5,950

Upper and Lower Limbs with hands and feet ... $890

Baby Skull matched to upper and lower limbs ... $595

Fetal Brains $2,230

Payments from One Customer to the Procurement Business for one Year

Exhibit F

38 Fetal Brains totaling $22,610

12 Fetal Hearts totaling $7,140

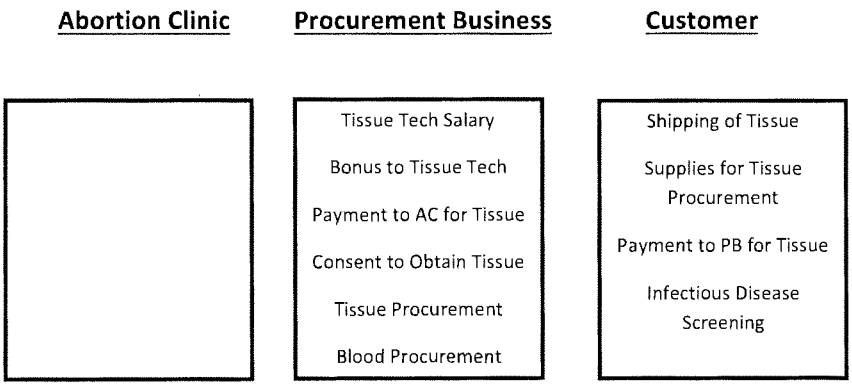
3 Fetal Upper/Lower Limbs totaling $2,670

5 Fetal Livers totaling $2,975

12 Fetal Pancreases totaling $7,140

For an annual total of: **$42,535**

Who Bears the Reasonable Cost of Tissue Procurement?



If the Abortion Clinic has no reasonable costs to be reimbursed, it raises an inference that it sold the human fetal tissue for a profit.

McDermott
Will & Emery

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Milan Munich New York Orange County Paris Rome Seoul Silicon Valley Washington, D.C.
Strategic alliance with MWE China Law Offices (Shanghai)

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April 19, 2016

DELIVERED VIA EMAIL

The Honorable Marsha Blackburn
Chair, Select Investigative Panel
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20510

The Hon. Jan Schakowsky
Ranking Member, Select Investigative Panel
House Energy & Commerce Committee
2322A Rayburn House Office Building,
Washington, DC 20515

Re: StemExpress Statement Regarding Select Investigative Panel and April 20, 2016 Hearing on "The Pricing of Fetal Tissue"

Dear Chairman Blackburn & Ranking Member Schakowsky:

On behalf of our client, StemExpress LLC ("StemExpress"),[1] enclosed please find a statement regarding the subject matter of the above-referenced hearing of the Select Investigative Panel. This document is Bates-stamped STEM.HOUSE.SELECT_0892-0907 and has not been marked as confidential.

If you have any questions about this correspondence, please do not hesitate to contact me at 202-756-8380.

Sincerely,

Amandeep S. Sidhu

Enclosure

[1] StemExpress is a privately held life sciences company that supports leading research institutions in the United States and internationally—including medical schools, pharmaceutical companies, and federal agencies—to provide stem cells and other human tissue critical to medical research. Cells produced by the physicians, scientists, medical technicians and nurses at StemExpress are currently used in research globally aimed at finding cures and treatments for cancer, diabetes, HIV/AIDS, cardiac disease, and other significant medical conditions. StemExpress plays a critical role in helping the global research community as they strive to achieve medical breakthroughs to stamp out global disease and improve quality of life.

cc (w/encl.):

March Bell, Select Panel Majority Staff Director
Heather Sawyer, Select Panel Minority Chief Counsel

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StemExpress Statement Regarding Select Investigative Panel's April 20, 2016 Hearing on "The Pricing of Fetal Tissue"

StemExpress was founded in 2010 by our CEO, Cate Dyer, with just $9,000. For the first few years, all of the money StemExpress made went directly back into the company. Despite offers from investors—including large venture capital firms, private equity groups, and pharmaceutical companies—Ms. Dyer controls 100 percent of StemExpress in order to maintain the company's focus on supporting researchers globally to produce better results for patients. Ms. Dyer believes that maintaining StemExpress as an independent company is critical to its ability to have the greatest impact on the research community.

StemExpress is dedicated to saving lives by providing researchers and research institutions specimens and products that accelerate the cure and prevention of significant medical conditions at life-changing speed. We believe that the current pace at which medical cures move to market is unacceptable, often citing the example that if a researcher discovered a cure for cancer today, it could take six to eight years to reach patients. While many researchers point to the heavy restrictions placed on research by regulatory agencies, the slow timeframe is overwhelmingly due to the amount of time it takes to source specimens, blood samples, and tissue needed for proper due diligence that is required by regulatory agencies. As a central source for research material, StemExpress is able to support hundreds of researchers at the same time. This allows StemExpress to make a positive and direct impact reducing human suffering around the globe.

I. StemExpress's Business Structure

StemExpress is a for-profit company but that does not mean that every product provided to researchers or research institutions is for profit. Some products are provided to clients for profit while other products are provided at cost or at a loss. Fetal tissue and cord blood are both provided at a loss. StemExpress has never profited—or received "valuable consideration" –from the provision of fetal tissue. It is also important to note that there are substantial expenses associated with running a business like StemExpress—some exemplar costs include (i) procuring blood and tissue for use in the manufacturing of isolated cells (including salaries and supplies); (ii) running our laboratory and manufacturing isolated cells (including salaries for highly trained staff and extremely expensive equipment); (iii) marketing and sales operations; and (iv) other general and administrative expenses.

II. StemExpress's Support for Fetal Tissue Research

Simply because StemExpress is a for-profit company does not mean that we do not participate in extensive philanthropic activities that result in no profit for the company. One example of this philanthropic activity is our support for fetal tissue research. As discussed in greater detail herein, the provision of fetal tissue is not only unprofitable, StemExpress incurs substantial financial losses in order to support the provision of fetal tissue. While most researchers

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working with fetal tissue or fetal cells also use adult human blood or tissue in their research, they consistently report better results in their work using fetal tissue. Researchers are generally aware that the use of fetal tissue may be controversial, so the choice to use fetal tissue is driven solely by the greater potential for scientific breakthroughs. There are also groups and individual activists that would prefer animals not be used in research. Both groups have large activist bases and have a history of causing significant harm to research institutions and individual researchers through laboratory bombings, harassment, harm to reputation, death threats, and even death. We know of no company, researcher, or scientist who does not think carefully and cautiously before deciding to use controversial material, tissue or cells in their work.

A good example of the research community specifically seeking fetal tissue is in response to the Zika virus.[1] The Centers for Disease Control and National Institutes of Health have publicly expressed the need to examine fetal tissue to determine how the Zika virus affects the fetus in the womb causing fetal brain damage and a study was recently published in the New England Journal of Medicine.[2] During the same period of time in which Congress has increased its criticism of fetal tissue research—and expressed doubt as to its practical implications—the Zika virus has become a global epidemic, spreading now to the United States. Many researchers throughout the medical community have shared with StemExpress that their institutions are waiting for the Select Panel to complete its investigation before going forward with additional fetal tissue research specific to the Zika virus and potential treatments.

III. Comparison to Organ Procurement Organizations

As a blood and tissue procurement organization, StemExpress modeled its tissue procurement operations after organ procurement organizations (OPOs). Like OPOs, StemExpress must either source tissue from hospitals and clinics or develop partnerships with entities where the company's personnel could be on the ground and perform the procurement role directly. Unlike OPOs, however, StemExpress does receive any reimbursement from Medicare for the procurement of cadaveric tissue. In contrast, OPOs receive substantial reimbursement on the basis of potential transplantation, regardless of whether transplant even takes place.

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[1] Alex Zielinski, *Fetal Tissue Research Uncovers New Information About Zika*, THINKPROGRESS (Mar. 31, 2016), http://thinkprogress.org/health/2016/03/31/3765233/fetal-tissue-zika-study/.

[2] R.W. Driggers, et al., *Zika Virus Infection with Prolonged Maternal Viremia and Fetal Brain Abnormalities*, NEW ENGL. J. MED. (Mar. 30, 2016), http://www.nejm.org/doi/pdf/10.1056/NEJMoa1601824.

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One tragic example that illustrates the difference between fetal and human tissue procurement is that of a mother donating her infant's organs in April 2014.[3] The infant was less than one-hour old. In this case, the mother consented, the organs were collected by a for-profit limited liability company in North Carolina and liver cells were isolated from the donated liver. Because this was a live birth, if only for less than one hour, this procurement was handled by an OPO and likely resulted in thousands of dollars of "reimbursements."

In most cases, if a tissue is "capable" at the time of collection of being transplanted, the payer will reimburse the procurement company, even if it turns out that tissue was not transplanted. On average those reimbursements are paid per organ or tissue and range from $20,000-$50,000 per specimen. These charges are assessed for transplantable organs, even if it is later determined that the tissue cannot be transplanted and the organ is sold for research purposes only. In comparison, the reimbursable fee paid by StemExpress of roughly $50-$75 per product of conception or organ that StemExpress provides back to the institutions involved in the procurement is drastically less than what would considered "normal" and reimbursed by the payers—either public or private—in the OPO transplant world.[4]

IV. StemExpress's Pricing of Fetal Tissue

When StemExpress was partnered with Planned Parenthood affiliates and in California, we had phlebotomists and other tissue procurement professionals on the ground in various clinics "on deck" to handle procurement based on the specific needs of our customers in research and industry. For example, procurement technicians were paid roughly $10-15/hour as "base" compensation and paid additional compensation based on the volume of blood or tissue procurement. Given the unpredictable nature of tissue procurement, *a procurement technician could often spend a full day at a clinic and collect no tissues.* Regardless of the whether we had 10 customer requests for a week or 50, we had to maintain staffing at clinics and incur that labor costs on a weekly basis. To the extent that a customer had a particularly difficult request—*e.g.*, tissue from a mother with a particularly rare disease—we might have had a procurement technician staffed at a clinic for weeks or months, waiting for that particular characteristic to meet the needs of the researcher. He or she would perform blood draws and be involved in other tissue procurement during this time.

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[3] Evelyn Grace Kittle, Donate Life, https://www.donatelifefloat.org/wp/2016-evelyn-grace-kittle/.

[4] *Review of Organ Acquisition Costs Claimed by Certified Transplant Centers*, Department of Health & Human Services Office of the Inspector General (Sept. 28, 2006), http://oig.hhs.gov/oas/reports/region9/90500034A.pdf (noting that in in a five-year period between 2000-2004, Medicare reimbursed $2.2 billion in organ acquisition costs, which is an average of $440 million annually).

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April 20, 2016 Hearing on "The Pricing of Fetal Tissue"

This labor overhead cost is a just one part of the overall cost and expenses that are incurred in the procurement of fetal tissue, which includes reasonable costs for processing, preservation, quality control, transportation, and storage of fetal tissue. Estimates of the total costs and expenses associated with the procurement of fetal tissue are detailed in Table A, below. These estimated costs—modeled on StemExpress technicians being in the clinics—includes the approximately $55 reimbursement that was paid to clinics for clinic staff time and use of space for consenting patients, obtaining blood draws, evaluating tissue, and storing procurement and shipping materials.

Table A: StemExpress Estimated Costs and Expenses Related to Fetal Tissue Procurement (2014-2015)

Item	Description	Time	Est. Costs/Expenses 2015	Est. Costs/Expenses 2014
Procurement Manager labor	Receive and evaluate purchase order, enter into company system and task board, assign to clinics	1 hour x $35	$ 35.00	$ 35.00
Packaging supplies	Packaging all supplies needed for procurement	1 hour x $10	$ 10.00	$ 10.00
FedEx	Supplies to clinic	N/A	$ 45.00	$ 45.00
Mileage	Mileage paid to technician (.56/mile)	N/A	$ 142.00	$ 142.00
Supply cost	Box, conical tube, media, petri dish, labels, biohazard bag, gel packs, etc.	N/A	$ 30.00	$ 30.00
Technician labor	Patient consent, procurement, paperwork, packaging	8 hours x $10	$ 80.00	$ 80.00
Technician compensation	Technician compensation	N/A	$ 50.00	$ 50.00
Clinic Reimbursement	Staff time, technician space, storage of supplies, blood draw chair usage, consent space	N/A	$ 55.00	$ 55.00
Infectious disease draw	Supplies: tubes, labels, needle, biohazard bag, etc	N/A	$ 15.00	$ 15.00
Infectious disease screening	Screening for HIV, HepB, HepC, LCMV	N/A	$ 155.00	$ 155.00
Shipping Charges	Average Shipment cost to the lab	N/A	$ 45.00	$ 45.00
Procurement Manager labor	Review paperwork, communications with courier, communications with researcher	1 hours x $35	$ 35.00	$ 35.00
Product Receipt	Receipt of product at front desk, check into company system, check into log	1 hour x $15	$ 15.00	$ 15.00
Inventory & Supply Management	Prorated stores management	1 hour x $20	$ 20.00	$ 20.00
TOTAL			$ 732.00	$ 732.00

These costs and expenses are an estimate, but are conservative in that no general overhead costs or any specific overhead, such as obtaining consent forms approved by an Independent Review Board (IRB), is included. These costs and expenses could also increase dramatically for a rare procurement that requires substantially more idle labor costs awaiting viable tissue.

Despite knowing that providing fetal tissue was going to result in financial losses, StemExpress has consistently charged less than non-profit entities that provide fetal tissue, as well.

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StemExpress Statement Regarding Select Investigative Panel's April 20, 2016 Hearing on "The Pricing of Fetal Tissue"

V. StemExpress Revenue and Costs Associated with Fetal Tissue

The majority of StemExpress's business involves isolating and purifying cells derived from donated tissue and blood. An exceedingly small portion of the company's revenue is derived from the provision of fetal tissue. For example, over the past several years revenue derived from fetal tissue has constituted roughly 1% of the company's total revenue before accounting for costs and expenses. Taking into account these cost and expenses, StemExpress operates in the red providing fetal tissue. From 2014 to 2015, StemExpress collected $74,955 in gross revenue from providing fetal tissue but incurred an estimated $95,160 in costs and expenses related to the processing, preservation, quality control, transportation, and storage of fetal tissue. The financial impact of these substantial costs is a two-year loss estimated at $20,205 on providing fetal tissue to clients. *See* Table B (below). The costs and expenses for 2011 through 2013 similarly exceed revenue, so StemExpress has always supported fetal tissue research at a financial loss.

Table B: StemExpress Fetal Tissue Revenue v. Estimated Costs/Expenses (2014-2015)

	2014	2015	TOTAL
Fetal Tissue Revenue (Actual)	$ 49,280.00	$ 25,675.00	$ 74,955.00
Fetal Tissue Costs/Expenses (Est.)	$ 62,220.00	$ 32,940.00	$ 95,160.00
Loss Incurred Supporting Fetal Tissue Research (Est.)	$ (12,940.00)	$ (7,265.00)	$ (20,205.00)

Some may ask why would we offer any service/product at a loss, and the answer is our mission statement – *StemExpress accelerates the cure and prevention of significant medical conditions at life changing speed.*

VI. StemExpress's Consent and Audit History

While the specific requirements for consent for fetal tissue donation vary from state to state, StemExpress utilizes consent forms approved by an Independent Review Board ("IRB") as a matter of course due to the high standards expected by our research customers. Unless specifically requested by a clinic or hospital to use an alternative informed consent form, StemExpress utilizes our own IRB-approved consents. We work with the clinics and other

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locations where we collect and procure blood and tissue to encourage them to default to our IRB-approved consent forms.

StemExpress is also the subject of regular audits, which is considered routine in the life sciences and biotech industries. In 2014, the U.S. Food and Drug Administration ("FDA") audited StemExpress and found no issues or violations in our practices. Despite the "all-clear" from the FDA, StemExpress was asked to deregister with the FDA because their oversight is limited to transplantable grade or clinical grade organizations, not procurement organization like StemExpress.

Our clients regularly audit us, as well, applying standards that vary from institution to institution. Some clients are ISO.9000 certified and some are not. Some have FDA oversight and some do not. We also work with international clients that are subject to unique country-specific laws. StemExpress has regularly defaulted to the high standards of federal agencies like the FDA and HHS to adopt best practices that set the standard for the tissue procurement industry.

The NEW ENGLAND JOURNAL of MEDICINE

BRIEF REPORT

Zika Virus Infection with Prolonged Maternal Viremia and Fetal Brain Abnormalities

R.W. Driggers, C.-Y. Ho, E.M. Korhonen, S. Kuivanen, A.J. Jääskeläinen, T. Smura, A. Rosenberg, D.A. Hill, R.L. DeBiasi, G. Vezina, J. Timofeev, F.J. Rodriguez, L. Levanov, J. Razak, P. Iyengar, A. Hennenfent, R. Kennedy, R. Lanciotti, A. du Plessis, and O. Vapalahti

SUMMARY

The current outbreak of Zika virus (ZIKV) infection has been associated with an apparent increased risk of congenital microcephaly. We describe a case of a pregnant woman and her fetus infected with ZIKV during the 11th gestational week. The fetal head circumference decreased from the 47th percentile to the 24th percentile between 16 and 20 weeks of gestation. ZIKV RNA was identified in maternal serum at 16 and 21 weeks of gestation. At 19 and 20 weeks of gestation, substantial brain abnormalities were detected on ultrasonography and magnetic resonance imaging (MRI) without the presence of microcephaly or intracranial calcifications. On postmortem analysis of the fetal brain, diffuse cerebral cortical thinning, high ZIKV RNA loads, and viral particles were detected, and ZIKV was subsequently isolated.

ZIKA VIRUS (ZIKV), A MOSQUITO-BORNE FLAVIVIRUS AND MEMBER OF THE Flaviviridae family, was originally isolated from a sentinel primate in Uganda in 1947.[1] ZIKV was associated with mild febrile disease and maculopapular rash in tropical Africa and some areas of Southeast Asia. Since 2007, ZIKV has caused several outbreaks outside its former distribution area in islands of the Pacific: in 2007 on Yap island in Micronesia, in 2013 and 2014 in French Polynesia, and in 2015 in South America, where ZIKV had not been identified previously.[2-5] There are separate African and Asian lineages of the virus,[6] and the latter strains have caused the outbreaks in the Pacific and the Americas.[7] As in the transmission of dengue and chikungunya viruses, the main transmission cycle of ZIKV occurs between urban aedes mosquitoes and humans.

One striking feature of the current ZIKV outbreak is the apparent increased risk of intrauterine or perinatal transmission of the virus as well as the marked increase in the number of newborns with microcephaly reported in Brazil.[8-17] A recent prospective study showed fetal ultrasonographic abnormalities in 12 of 42 women (29%) with ZIKV infection during pregnancy; 7 of the 42 fetuses (17%) that were studied had microcephaly, cerebral atrophy, or brain calcifications.[11] Because of the association between ZIKV infection and microcephaly and other neurologic disorders, the World Health Organization has declared the ZIKV epidemic a public health emergency of international concern.[13]

Early in this particular outbreak, investigations into the viral pathogenesis, vertical transmission rates, potential viral cofactors, and sensitivity and specificity of diagnostic testing have presented more questions than answers. Nevertheless,

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Drs. Driggers and Ho, Ms. Korhonen, and Ms. Kuivanen and Drs. du Plessis and Vapalahti contributed equally to this article.

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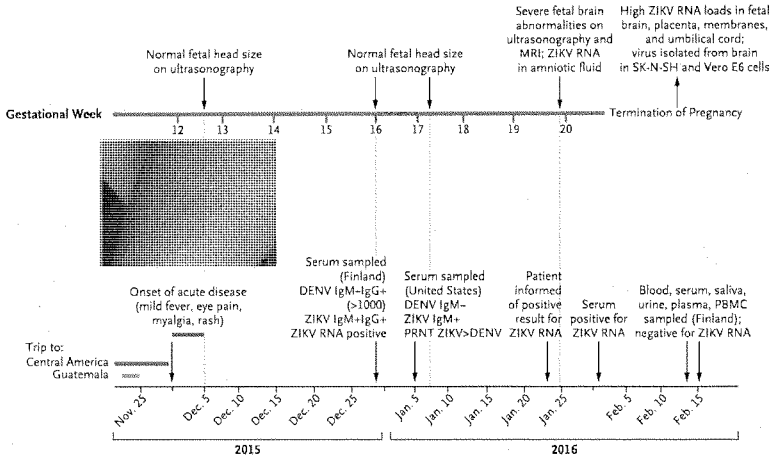

Figure 1. Timeline of Symptoms and Radiographic and Laboratory Studies.

This timeline highlights the symptoms of Zika virus (ZIKV) infection in the mother (bottom row) and the corresponding radiographic and laboratory findings in the fetus (top row). The inset photograph shows the mother's rash at the time of the onset of the acute illness. DENV denotes dengue virus, MRI magnetic resonance imaging, PBMC peripheral-blood mononuclear cells, and PRNT plaque-reduction neutralization test.

the Centers for Disease Control and Prevention (CDC) has issued a travel advisory for pregnant women,[15] as well as guidelines for health providers caring for all travelers from affected regions.[16,17] The CDC recommends that pregnant women with a history of travel to an area in which ZIKV is endemic should undergo ZIKV serologic testing and fetal ultrasonography to screen for microcephaly or intracranial calcifications.[16] For a diagnosis of fetal ZIKV infection, RNA detection in amniotic fluid may be considered in pregnant women with positive results on ZIKV serologic testing.[16] Here we present a report of a case of congenital ZIKV infection and subsequent findings in a pregnancy that was terminated at 21 weeks of gestation.

CASE REPORT

A 33-year-old Finnish woman who was in the 11th week of gestation was on holiday in Mexico, Guatemala, and Belize with her husband in late November 2015. (Details are provided in Section 1.0 of the Supplementary Appendix, available with the full text of this article at NEJM.org.) During their travels, she and her husband recalled being bitten by mosquitoes, particularly in Guatemala. One day after her arrival at her current residence in Washington, D.C., she became ill with ocular pain, myalgia, and mild fever (maximum, 37.5°C), which lasted for 5 days. On the second day of fever, a rash developed (Fig. 1, and Fig. S5 in the Supplementary Appendix). Her husband was concomitantly reporting similar symptoms. Serologic analysis that was performed 4 weeks after the onset of illness while she was on a trip to her native Finland was positive for IgG antibodies and negative for IgM antibodies against dengue virus. Subsequent serologic analysis was positive for both IgG and IgM antibodies against ZIKV, findings that were compatible with acute or recent ZIKV infection. Serologic analysis for the presence of chikungunya virus was negative. The patient had been vaccinated against tick-borne

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encephalitis and yellow fever more than 10 years earlier.

Fetal ultrasonography that was performed at 13, 16, and 17 weeks of gestation (1, 4, and 5 weeks after the resolution of symptoms) showed no evidence of microcephaly or intracranial calcifications. However, there was a decrease in the fetal head circumference from the 47th percentile at 16 weeks to the 24th percentile at 20 weeks.

At 16 weeks of gestation, the presence of flavivirus in serum was detected on nested reverse-transcriptase–polymerase-chain-reaction (RT-PCR) assay, and sequencing showed identity to Central American epidemic strains of ZIKV. The finding was confirmed with a specific ZIKV quantitative RT-PCR assay (Table S2 in the Supplementary Appendix). The Division of Vector-Borne Diseases Arbovirus Diagnostic Laboratory at the CDC reported serologic evidence of infection at 17 weeks of gestation, with serum positivity for ZIKV IgM and a titer of more than 1:2560 on a plaque-reduction neutralization test. On the basis of these results, the patient sought more thorough assessment of the fetus.

Fetal ultrasonography at 19 weeks of gestation showed abnormal intracranial anatomy (Fig. 2, and Fig. S1 in the Supplementary Appendix). The cerebral mantle appeared to be thin with increased extra-axial spaces. Both frontal horns were enlarged with heterogeneous, predominantly echogenic material present in the frontal horn and body of the left lateral ventricle, a finding that raised concern about intraventricular hemorrhage. Dilation and upward displacement of the third ventricle, dilation of the frontal horns of the lateral ventricles, concave medial borders of the lateral ventricles, and the absence of the cavum septum pellucidum suggested agenesis of the corpus callosum. No parenchymal calcifications were seen. The head circumference measured in the 24th percentile for gestational age. The remainder of the fetal anatomy was normal.

Fetal MRI at 20 weeks of gestation showed diffuse atrophy of the cerebral mantle, which was most severe in the frontal and parietal lobes, with the anterior temporal lobes least affected (Fig. 3). The normal lamination pattern of the cerebral mantle was absent, and the subplate zone was largely undetectable. The corpus callosum was significantly shorter than expected for gestational age, with an anterior–posterior length of 14 mm (expected range, 18 to 22).[18,19] The cavum septum pellucidum was very small. The lateral ventricles were mildly enlarged, as was the third ventricle, with a transverse diameter measuring 2.5 mm (average measurement at gestational age, 1.75 mm [range, 1.1 to 2.3]).[18] The fourth ventricle was normal. The volume of the choroid plexus was unusually prominent, without evidence of hemorrhage. No focal destructive lesions were identified within the cerebral cortex or white matter. The cerebellum was normal in appearance and size. Given the grave prognosis,

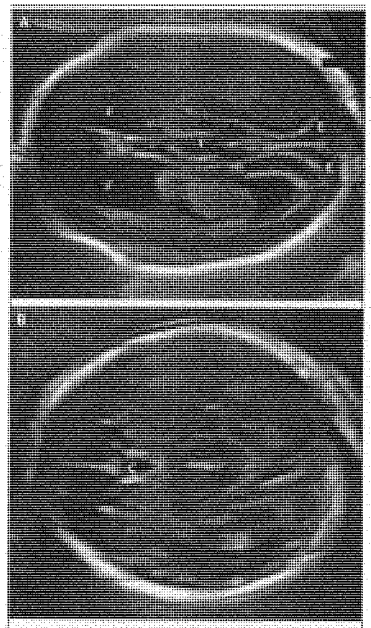

Figure 2. Fetal Ultrasonography at 19 Weeks of Gestation.

In an ultrasonographic image of the brain of the Zika-exposed fetus in this report (Panel A), there are a thin cerebral cortex with increased extra-axial space (E), dilation of the third ventricle (T), enlargement of both frontal horns (F), and the apparent absence of the cavum septum pellucidum, as compared with an image obtained in a normal fetus of the same gestational age with a visible cavum septum pellucidum (C) (Panel B).

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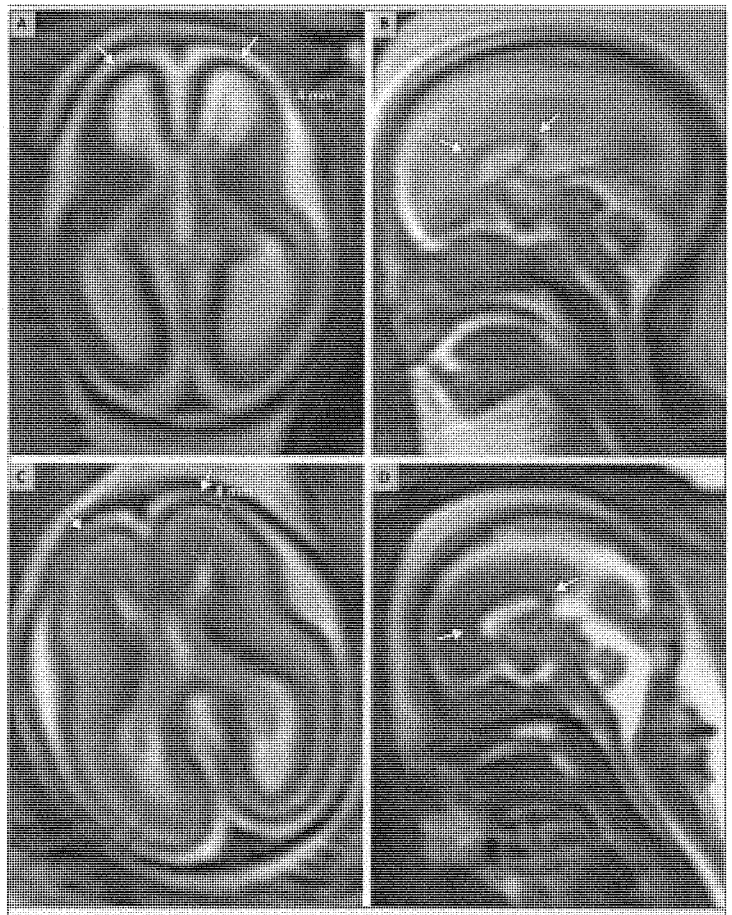

Figure 1. Magnetic Resonance Imaging of the Fetal Brain at 29 Weeks of Gestation.

On T2-weighted imaging of the brain of the 20Cr-exposed fetus, a 3-mm-thick axial view (Panel A) shows severe atrophy of the cerebral mantle, which was most visible in the frontal regions (arrows) where the cortical mantle measures 1.4 mm. In a 3-mm-thick midline sagittal image (Panel B), the small corpus callosum (arrow) is visible, with an anterior–posterior length of 14 mm (normal range, 18 to 33).[7,8] Below are matching images of the same fetus and thicknesses in a normal fetus with a gestational age of 29 weeks 1 days, showing the cortical mantle measuring 8 mm (in Panel C) and the corpus callosum measuring 30 mm (in Panel D).

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the patient elected to terminate the pregnancy at 21 weeks of gestation.

METHODS

We tested samples obtained from the patient, her spouse, and the fetus and from viral isolation trials for ZIKV RNA using nested pan-flavivirus RT-PCR and quantitative RT-PCR for ZIKV. Levels of ZIKV IgM, IgG, and neutralizing-antibody titers were determined by means of standard methods. We performed immunohistochemical and electron microscopic analyses to study fetal brain tissue. Viral isolation trials using the patient's serum and fetal tissues were performed with the use of SK-N-SH human neuroblastoma cells, Vero E6 green monkey kidney cells, and C6/36 *Aedes albopictus* mosquito cells. We used next-generation sequencing and Bayesian analysis to study the genetics of the ZIKV strain isolate. Additional details about the analyses are provided in the Methods section of the Supplementary Appendix.

RESULTS

FETAL NEUROLOGIC ABNORMALITIES

A postmortem examination was performed with materials collected for additional study. Gross examination showed normal fetal anatomy and severe autolysis. The brain weighed 30 g (reference weight, 49±15[20]) and showed no apparent gross abnormalities. Microscopic analysis revealed abundant apoptosis primarily affecting the intermediately differentiated postmigratory neurons in the neocortex (Fig. 4, and Fig. S2 in the Supplementary Appendix). Early mineralization was seen in association with apoptotic neurons focally. In contrast, the well-differentiated neurons of the basal ganglia and limbic regions as well as primitive cells in the germinal matrix appeared to be unaffected.

In addition to the cortical neuronal abnormalities, the subventricular zone and white matter showed severe volume loss with extensive axonal rarefaction and macrophage infiltrates (Fig. 4). This pattern correlates with the atrophy of the subplate seen on prenatal imaging. There was diffuse infiltration of macrophages in the cerebral cortex, subventricular zone, white matter, and leptomeninges but not in the germinal matrix of the ganglionic eminence. Scattered loose microglial aggregates were observed in the deep gray matter and brain stem, but there was no evidence of well-formed microglial nodules or other classic histologic features of viral encephalitis, such as perivascular inflammatory infiltrates, viral inclusions, or ventriculitis. Ultrastructural examination of fixed cortical tissue showed a rare aggregate of intracellular electron-dense, viral-like particles that measured 39 to 41 nm in diameter (mean, 40.26). Our ability to specifically localize the cellular compartment housing the particles was limited by poor tissue preservation, but the morphologic features and size of this structure were similar to those reported by Mlakar et al.[10] and the CDC.[21] The choroid plexus was focally enlarged and edematous, with scant hemosiderin deposits, which may appear to be similar to intraventricular hemorrhage on prenatal imaging. Histologic examination of the eyes, spinal cord gray matter, dorsal-root ganglia, and spinal nerves did not reveal overt microscopic abnormalities. Spinal white-matter tracts were not well visualized. A detailed pathological description of the brain and other organs is provided in the Methods section of the Supplementary Appendix.

FETAL AND MATERNAL ZIKV VIRAL LOADS

The highest ZIKV viral loads were found in fetal brain, with substantial viral loads in the placenta, fetal membranes, and umbilical cord, as studied on quantitative RT-PCR (Table S2 in the Supplementary Appendix). Lower amounts of ZIKV RNA were found in fetal muscle, liver, lung, and spleen. Amniotic fluid that was obtained at the time of termination was positive for ZIKV RNA with low viral counts. On PCR assays to detect DNA, the amniotic fluid was negative for parvovirus B19, herpes simplex virus types 1 and 2, cytomegalovirus (CMV), and *Toxoplasma gondii*, and the fetal brain tissue was negative for herpes simplex virus types 1 and 2 and varicella–zoster virus.

Maternal serum that was obtained on the day before termination was also positive for ZIKV RNA with a low viral count (2.1×10^3 copies per milliliter). No ZIKV RNA was detected in the serum, peripheral-blood mononuclear cells, saliva, or urine in samples obtained 11 days and 13 days after termination. On IgM analysis, the mother had no evidence of serum antibodies indicating acute infection with CMV, parvovi-

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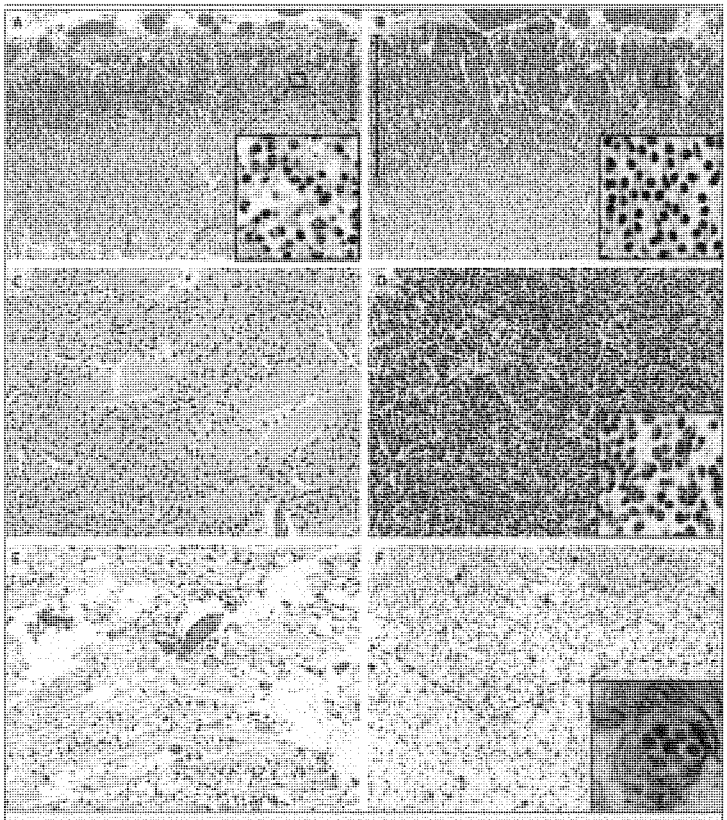

Figure 4. Neuropathological Features of Fetal ZIKV Infection.

In postmortem analysis of samples obtained from the fetus, an area of parietal cortex has abundant apoptotic neurons (Panel A), with detail shown in the inset view. The unaffected occipital cortex is thicker than the parietal cortex (Panel B), as indicated by the vertical bars. The basal ganglia (striatum) appears to be morphologically normal (Panel C), and cells in the germinal matrix of the ganglionic eminence are histologically normal (Panel D). White matter shows extensive axonal rarefaction and infiltrates of macrophages containing foamy cytoplasm and cellular debris in some cells (Panel E) (hematoxylin and eosin staining in Panels A through E). Panel F shows macrophage infiltrates in the cortex (area above the dashed line) and subcortical white matter (area below the dashed line) (anti-CD68 immunostaining with hematoxylin counterstaining). The inset shows possible viral-like particles within a subcellular compartment, as seen on electron microscopy.

rus B19, *T. gondii*, or rubella virus. Samples obtained from her spouse were all negative for ZIKV RNA, including urine (obtained 11 weeks after travel), serum (obtained 5 and 11 weeks after travel), and semen (obtained 10 and 12 weeks after travel), although results of testing for ZIKV IgG (titer 320) and IgM (titer 20) were positive.

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VIRUS ISOLATION

ZIKV replication was detected as an increase in ZIKV RNA on quantitative RT-PCR assay of SK-N-SH and Vero E6 cells inoculated with the fetal brain sample. The quantities of ZIKV RNA increased rapidly in the SK-N-SH cells after the first day of inoculation, whereas in the Vero E6 cells, viral RNA loads started to increase on day 4 after inoculation. Viral replication was not detected in cells inoculated with other samples. The tissue-inoculated SK-N-SH and Vero E6 cells were further shown to express ZIKV antigens by reactivity with human convalescent anti-ZIKV serum (obtained from the father of the fetus) on immunofluorescence staining and to produce flavivirus-like particles, as seen on electron microscopy (Fig. 5).

A complete ZIKV genome was sequenced from supernatant of SK-N-SH cells on day 5 after inoculation. Phylogenetic analysis indicated that the viral strain (designated ZIKV_FB-GWUH-2016; GenBank number, KU870645) was a member of the Asian genotype and closely related to two ZIKV sequences obtained from Guatemalan patients who presented with mild illness (Fig. 6, and Fig. S6 in the Supplementary Appendix).[7] The FB-GWUH-2016 strain had 23 to 51 nucleotide differences and 8 to 14 amino acid differences as compared with the ZIKV strains detected previously in the Americas (99.6 to 99.8% identities) (Fig. 5D). Five of the eight differences in amino acids between FB-GWUH-2016 and the Guatemalan strains were specific for the FB-GWUH-2016 strain (i.e., differences that were not detected in other ZIKV strains sequenced so far). One amino acid substitution was a reversion toward the African ZIKV genotype. Three amino acid substitutions were common for FB-GWUH-2016 and the Guatemalan strains but distinct from all other reported ZIKV strains.

DISCUSSION

The current recommendations for ZIKV diagnostic practices are based on the understanding that ZIKV viremia lasts for less than a week after the onset of infection.[15] During the week of symptomatic infection, RNA detection in serum or blood is considered to be the diagnostic method of choice. ZIKV RNA can be detected in urine for some days longer.[22,23] ZIKV is also present in semen for an unknown length of time, and scattered reports of sexual transmission of ZIKV have emerged.[24-28] ZIKV RNA testing is not recommended for pregnant women after the first week after the onset of clinical disease. The diagnosis is usually based on a ZIKV-specific antibody response with higher IgM and neutralizing-antibody responses to ZIKV than to other flaviviruses.[13] However, we have detected ZIKV RNA in the serum of a pregnant woman at 4 weeks and 10 weeks after the clinical onset of ZIKV infection but not after delivery. We suspect that the persistent ZIKV viremia in the patient described here was a consequence of viral replication in the fetus or placenta, which had high viral loads. Therefore, in addition to current ZIKV diagnostics, the use of quantitative RT-PCR methods may be a potential diagnostic approach for ongoing placental or fetal infections in pregnant women. Notably, in this patient, the ZIKV RNA levels were slightly higher in the maternal serum than in the amniotic fluid. The dynamics of ZIKV RNA in the serum of infected pregnant women are not well understood and will need to be assessed in larger studies.

It is estimated that 80% of ZIKV infections are asymptomatic.[29] Although the evidence of the association between the presence of ZIKV in pregnant women and fetal brain abnormalities continues to grow, the timing of infection during fetal development and other factors that may have an effect on viral pathogenesis and their effects on the appearance of brain abnormalities on imaging are poorly understood. Oliveira Melo et al.[9] described two cases of ZIKV intrauterine infection associated with microcephaly and brain calcifications that were diagnosed by means of ultrasonography during the third trimester. Similar to the fetus in our report, the two fetuses in that study showed abnormal development of the corpus callosum and decreased brain parenchymal volume. In the case described by Mlakar et al.,[10] the results of ultrasonography that was performed at 14 weeks and 20 weeks of gestation were normal, but microcephaly, ventriculomegaly, and calcifications were seen on ultrasonography at 29 weeks of gestation.[10] In the larger Brazilian cohort, cerebellar atrophy was seen in a fetus at 20 weeks of gestation, but microcephaly was not diagnosed until 27 to 35 weeks in their cohort.[11] In our study, a review of three sequential ultrasonographic images between 16 and 20 weeks showed a decrease in the fetal head circumferences from the 47th percentile to the 24th percentile, which suggests a reduction in the rate of

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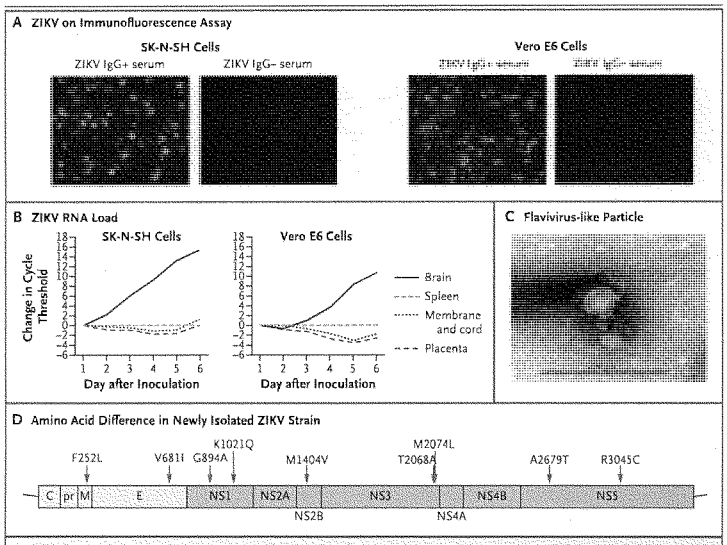

Figure 5. Isolation of ZIKV from Fetal Brain Tissue, ZIKV Growth in Fetal Tissues, Electron Microscopy of a Flavivirus-like Particle, and Amino Acid Differences in the Newly Isolated Strain.

Panel A shows immunofluorescence assays of human neuroblastoma cells (SK-N-SH) and Vero E6 cells that were inoculated with fetal tissue samples to determine the presence of ZIKV. The samples were shown to express ZIKV antigens by reactivity with human convalescent anti-ZIKV serum (ZIKV IgG-positive and IgG-negative [control] samples; dilution, 1:40) obtained from the father. Antihuman IgG fluorescein isothiocyanate conjugate was used as a reagent. Panel B shows the growth curve of ZIKV in SK-N-SH and Vero E6 cells on RT-PCR, indicating the change in ZIKV RNA loads (as determined by the change in cycle threshold) in cell cultures after inoculation with samples from fetal brain, spleen, membrane and cord, and placenta. Panel C shows an electron microscopic image of a particle resembling a flavivirus from supernatant of SK-N-SH cells inoculated with fetal brain tissue. Panel D shows amino acid differences between the FB-GWUH-2016 isolate of ZIKV in this study and the related Guatemalan ZIKV strains (red arrows) and the amino acids that were identical in the study isolate and the related strains but distinct from all other known epidemic strains (blue arrows).

brain growth during that period (Fig. S3 in the Supplementary Appendix). We suspect these reductions in brain growth would have eventually met the criteria for microcephaly. As this case shows, the latency period between ZIKV infection of the fetal brain and the detection of microcephaly and intracranial calcifications on ultrasonography is likely to be prolonged. Negative ultrasonographic studies during this period would be falsely reassuring and might delay critical time-sensitive decision making. Serial ultrasonographic measurements of head circumference may provide useful predictive information. The superior soft-tissue resolution of fetal brain MRI might be more sensitive to developmental and encephaloclastic changes, thereby expediting the detection of evolving fetal brain anomalies.

This case is an early foray into the histopathological findings associated with ZIKV in the midgestational fetal brain. The overwhelming findings were of loss of intermediately differentiated postmigratory neurons through an apoptotic mechanism. There appeared to be preservation of more differentiated neurons in basal ganglia, limbic region, and dorsal spinal cord. The germinal matrix cells also appeared to be spared.

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Of note, the germinal matrix consists predominantly of glioblasts at midgestation with the majority of the neuroblasts having already migrated out of the zone. Although we could not evaluate neuronal precursor subtypes other than calretinin-expressing interneuron lineage cells, selective neuronal vulnerability to ZIKV injury requires further investigation.

The successful isolation of infectious ZIKV from human fetal brain fulfills Koch's second postulate regarding the isolation of pathogens from a diseased organism and strengthens the association between congenital ZIKV infection and fetal brain damage. Although ZIKV RNA was found in several fetal organs and the placenta, the virus could be isolated only from brain tissue. The rapid isolation in a human neuroblastoma cell line suggests a predilection of the ZIKV strain for human neural lineage cells. This hypothesis is in line with the histopathological findings and the results of a recent study showing a high rate of ZIKV infection in cortical neural progenitor cells but not in embryonic or pluripotent stem cells.[30] The close genetic relationship between the isolate in our report and Guatemalan ZIKV strains was consistent with the anamnestic knowledge on the likely geographical origin of the infection. We found a relatively high frequency of nonsynonymous mutations between the FB-GWUH-2016 genome and the Guatemalan ZIKV genome (Fig. S4 in the Supplementary Appendix), a finding that could indicate viral adaptation to growth in the fetal brain. However, no amino acid changes were identical to previously reported alterations in the ZIKV genome sequenced from fetal brain tissue.[10]

In conclusion, our study highlights the possible importance of ZIKV RNA testing of serum obtained from pregnant women beyond the first week after symptom onset, as well as a more detailed evaluation of the fetal intracranial anatomy by means of serial fetal ultrasonography or fetal brain MRI. The isolation of ZIKV from fetal brain provides additional evidence for the association between congenital ZIKV infection and fetal brain damage and provides tools for further studies of the pathogenesis of ZIKV-induced microcephaly. Future studies at various gestational ages will offer better insight into the role of ZIKV infection in abnormal brain development and provide markers for its detection.

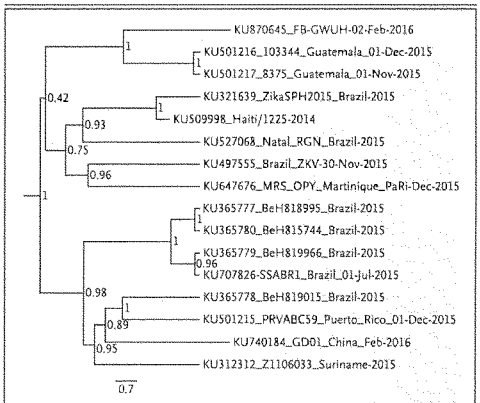

Figure 6. Phylogenetic Tree Showing Newly Isolated ZIKV Strain.

The FB-GWUH-2016 ZIKV strain that was isolated in the fetal brain in this case report is shown at the top of a phylogenetic tree, which was constructed with the use of the Bayesian Markov chain Monte Carlo method. A subclade of Asian lineage that contains the American ZIKV strains is shown. Viral strains are listed according to country and year of collection. The scale bar shows the nucleotide sequence divergence. An expanded phylogenetic tree showing the complete coding regions of ZIKV strains (as of February 28, 2016) is provided in Fig. S6 in the Supplementary Appendix.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank the patient and her husband for their support of our study; Irina Suomalainen, Inkeri Luoto, and Sanna Mäki of the University of Helsinki for their technical assistance; Tamas Baszinka and Kirsi Aaltonen for their help in preparing samples; Dr. Eili Huhtamo for guidance in setting up the nested RT-PCR assay; the Finnish IT Center for Science for the allocation of computational resources; and Yvette Veloso, Mandy Field, and Laurie King for their technical support.

APPENDIX

The authors' full names and academic degrees are as follows: Rita W. Driggers, M.D., Cheng-Ying Ho, M.D., Ph.D., Essi M. Korhonen, M.Sc., Suvi Kuivanen, M.Sc., Anne J. Jääskeläinen, Ph.D., Teemu Smura, Ph.D., Avi Rosenberg, M.D., Ph.D., D. Ashley Hill, M.D., Roberta L. DeBiasi, M.D., Gilbert Vezina, M.D., Julia Timofeev, M.D., Fausto J. Rodriguez, M.D., Lev Levanov, Ph.D., Jennifer Razak, M.G.C., C.G.C, Preetha Iyengar, M.D., Andrew Hennenfent, D.V.M., M.P.H., Richard Kennedy, M.D., Robert Lanciotti, Ph.D., Adre du Plessis, M.B., Ch.B., M.P.H., and Olli Vapalahti, M.D., Ph.D.

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Boston Brussels Chicago Dallas Düsseldorf Frankfurt Houston London Los Angeles Miami
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April 19, 2016

DELIVERED VIA EMAIL

The Honorable Marsha Blackburn
Chair, Select Investigative Panel
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20510

The Hon. Jan Schakowsky
Ranking Member, Select Investigative Panel
House Energy & Commerce Committee
2322A Rayburn House Office Building,
Washington, DC 20515

Re: Call for Withdrawal or Amendment of Proposed Exhibits for April 20, 2016 Hearing on "The Pricing of Fetal Tissue"

Dear Chairman Blackburn & Ranking Member Schakowsky:

On behalf of our client, StemExpress LLC ("StemExpress"),[1] this letter responds to the exhibits that we understand that the Majority members of the Select Investigative Panel ("Select Panel") intend to use at the April 20 hearing entitled "The Pricing of Fetal Tissue."

Our client has reviewed the Majority's proposed exhibits and confirmed a number of issues that should gravely concern you and the witnesses that are slated to appear at tomorrow's hearing. These issues raise questions about the authenticity and validity of several of these documents, which we understand have already been circulated to the witnesses and relied upon in their respective opening statements (which are now publicly available on the Select Panel's website). In light of the issues raised in this letter, we strongly suggest that the Majority consider rescinding or revising its exhibits to avoid reliance on questionable documents that could easily be vetted with StemExpress personnel, several of whom have been offered up for depositions or issued subpoenas by the Select Panel.

[1] StemExpress is a privately held life sciences company that supports leading research institutions in the United States and internationally—including medical schools, pharmaceutical companies, and federal agencies—to provide stem cells and other human tissue critical to medical research. Cells produced by the physicians, scientists, medical technicians and nurses at StemExpress are currently used in research globally aimed at finding cures and treatments for cancer, diabetes, HIV/AIDS, cardiac disease, and other significant medical conditions. StemExpress plays a critical role in helping the global research community as they strive to achieve medical breakthroughs to stamp out global disease and improve quality of life.

Potential Use of Stolen Documents as "Evidence"

While several of the Majority's exhibits masquerade as redacted StemExpress documents—cited as being sourced from a "procurement business"—it is not clear whether they are derived from the nearly 900 pages of materials that were produced by StemExpress with Bates stamping and conspicuous confidentiality legends. Instead, it appears that the Majority Staff may have repurposed unauthenticated, stolen documents illegally obtained by David Daleiden and the Center for Medical Progress ("CMP"). Mr. Daleiden has admitted under oath that he used the password of Holly O'Donnell, a former StemExpress contractor, to illegally gain unauthorized access to StemExpress's email system to steal electronic documents. *See* Ex. A, Daleiden Dep. 286:8-288:12, Dec. 30, 2015, *StemExpress LLC, et al. v. Daleiden, et al.*, Case No.BC589145 (Ca. Sup. Ct.). These actions constitute violations of both California and federal law. *See, e.g.*, 10 U.S.C. § 1030.

While some of these illegally obtained documents are posted to the CMP website, some of the Majority's exhibits have never appeared publicly, suggesting that perhaps the Select Panel may be receiving so-called "evidence" directly from Mr. Daleiden and/or his associates. At least one document, Exhibit C3, appears to be a screenshot taken by some unknown person who nefariously accessed the *administrator* portion of StemExpress's "WordPress" website builder. Other documents appear to have been created by Mr. Daleiden's fake tissue procurement company, BioMax, which was established using false identification and falsified documents. Mr. Daleiden and his associate, Susan Merritt, are currently the subject of indictments in Texas and an ongoing investigation in California that will likely result in additional indictments.

- **Ex. C3:** As noted above, this screenshot appears to have been taken by someone who illegally hacked into the administrator access portal of StemExpress's website or otherwise accessed the administrator site without permission. It was not produced by StemExpress and, therefore, cannot be authenticated by the Select Panel.

- **Exs. C4 through C14:** Nearly all of these documents appear to be versions of StemExpress documents that were stolen by David Daleiden and posted to the Center for Medical Progress website. While some of the materials may also have been produced by StemExpress to the Select Panel, the Majority has inexplicably removed the Bates stamping that would have allowed for immediate validation.

StemExpress has never been asked to verify the authenticity of any of these documents or respond to any questions that the Select Panel might have regarding these materials. Any opinions rendered by the panel of witnesses at tomorrow's hearing will be built upon a foundation of illegally obtained evidence and exhibits of questionable utility and merit. In light of the forgoing, we respectfully request that exhibits that appear to be derived from stolen materials be withdrawn until the General Counsel of the House of Representatives, Kerry W.

Kircher, authorizes and approves the use of illegally obtained materials by a person currently under indictment.

Failure to Redact Identifying Information

Despite repeated assurances from the Majority Staff that you are not concerned with "naming names," several of the Majority's proposed exhibits leave the names of companies and researchers unredacted. For example:

- **Ex. C3:** Includes partial name of StemExpress in top left corner of screenshot.
- **Ex. C4:** Includes the names of both individual researchers and StemExpress customers throughout document.
- **Ex. C13:** Includes the names of StemExpress customers throughout document.

Just a few weeks ago, the Majority failed to redact the name of a StemExpress employee who received a subpoena. Only after being alerted to the issue by counsel for StemExpress and the Minority staff did the Select Panel grudgingly replace the public copy of the subpoena with a redacted version. The gravity of our concerns about safety and security was amplified today when Scott Orton pleaded guilty in California federal district court to transmitting interstate threats to kill an officer of StemExpress last summer. *See* Ex. B (DOJ Press Release). Accordingly, due to the grave safety and security risk posed by the Select Panel's public scrutiny, we respectfully request that these names be redacted prior to further dissemination or, certainly, before making these documents public.

Failure to Conduct Even Cursory Investigation Regarding Pricing and Cost/Expenses

Through Exhibit B4, the Majority appears to reference publicly reported total revenue numbers for StemExpress. In each instance, any "total revenue" number is inclusive of all StemExpress products, which includes "human blood, tissue products, bone marrow, primary cells, and the clinical specimens they need to perform their research." *Id.*

In fact, fetal tissue revenue is an exceedingly small fraction of StemExpress's total revenue in any given year. Any revenue derived from fetal tissue must be offset by reasonable costs and expenses related to the processing, preservation, quality control, transportation, and storage of fetal tissue. For example, StemExpress's 2014 total revenue consisted of less than $50,000 from the sale of fetal tissue to researchers (as reflected in the Majority's own Exhibit F, produced by StemExpress). Despite accounting for only 1% of total revenue, StemExpress incurred approximately $62,000 in costs and expenses related to the processing, preservation, quality control, transportation, and storage of fetal tissue. *In other words, StemExpress lost roughly $13,000 in order to provide fetal tissue to researchers in 2014.* Similarly, in 2015, StemExpress had just under $26,000 in revenue from fetal tissue and incurred approximately $33,000 in cost and expenses, *resulting in a net loss of roughly $7,000.*

As reflected in the table below, over a two-year period StemExpress's revenue derived from fetal tissue accounted for just under $75,000—roughly 1% of the company's total revenue, 99% of which is derived from non-fetal tissue sources—and resulted in $95,000 in costs and expenses, for a total loss of over $20,000.

StemExpress Fetal Tissue Revenue v. Estimated Costs/Expenses (2014-2015)

	2014	2015	TOTAL
Fetal Tissue Revenue (Actual)	$49,280	$25,675	$74,955
Fetal Tissue Costs/Expenses (Est.)	$62,220	$32,940	$95,160
Loss Incurred Supporting Fetal Tissue Research (Est.)	**($12,940)**	**($7,265)**	**($20,205)**

In short, StemExpress does not provide fetal tissue to its customers to make money; rather, it is offered to support the needs of the world's best researchers in their efforts to treat and cure diseases. There can be no argument that StemExpress received "valuable consideration" for the sale of fetal tissue, pursuant to 42 U.S.C. § 289 g-2(a) and (e)(3).

Gross Inaccuracies, Manipulation of Evidence, and Misstatements of Facts

Several of the proposed exhibits appear to force the Majority's views into the record in a way we have never seen in any government investigation in the House, Senate, or across dozens of federal and state jurisdictions around the United States. Below is a limited list of issues with several of the exhibits:

- **Ex. A2:** This overly simplistic, Majority-created chart suggests that a for-profit company like StemExpress cannot support not-for-profit charitable projects, including the sale of fetal tissue at a financial loss. The Majority fails to note that StemExpress consistently charges *less* for fetal tissue than its not-for-profit competitors in the marketplace.

- **Ex. B1:** This Majority-created chart asks questions that have *never been posed to StemExpress*. While some of the questions have been answered by prior responses and productions, StemExpress is providing the Select Panel with additional information reflecting the significant losses from the sale of fetal tissue from 2011 through 2015. See Ex. B5, below, for detailed discussion regarding StemExpress's losses related to fetal tissue sales.

- **Ex. B2:** The Majority's use of this brochure is misleading, at best. It was used by StemExpress with hospitals and clinics involved in the broad spectrum of work that

company supports related to adult blood, adult tissue, biopsies, etc. – *not only fetal tissue donation.*

- **Ex. B3:** This StemExpress website screenshot makes *absolutely no reference to fetal tissue*. In fact, it pertains to the overwhelming majority of StemExpress's work with adult blood and tissue that has *nothing to do with fetal tissue*, which accounted for *less than one percent* of the company's revenue in 2014, *before losses*.

- **Ex. B4:** This document does not appear to have any basis in evidence or reality. The chart alleges that the "procurement business" in question over 50 clinic partnerships in 2013, nearly 100 in 2014, and over 250 in 2015. In reality, StemExpress has partnered with no more than a dozen clinics for fetal tissue donation at any point between 2010 and 2015, inclusive of relationships with Planned Parenthood and independent clinics.

- **Ex. B6:** This National Abortion Federal agreement appears to have been altered and manipulated to remove references to legal provisions and other terms of the agreements. It is deliberately misleading and incomplete.

- **Ex. C1:** This document, created by the Majority Staff, is factually inaccurate. At the time that StemExpress personnel were working in clinics, they neither reviewed patient medical files nor discussed tissue needs with the clinic prior to meeting with patients to obtain consent for donation. If the Majority had elected to conduct interviews of one or more of the witnesses repeatedly offered by StemExpress, questions such as these could have been answered.

- **Ex. C2:** This document, also created by the Majority Staff, is replete with misstatements and inaccuracies. For example, StemExpress does not obtain approval from an Independent Review Board ("IRB") after a tissue order is placed. Rather, the role of the IRB is to validate consent forms that are used for donation across a broad range of tissue types, including fetal tissue, before donation occurs. The IRB-approved consent forms are on file and in use when a customer places an order.

- **Exs. D1 through D3:** These invoices reflect charges for maternal blood and products of conception ("POCs"), which includes both placental *and* fetal tissue. The charges for POCs are collapsed into one line item, but the actual number of fetal tissue collections was far smaller than the overall volume of placental (non-fetal) POC collections.

* * * * *

From the outset of this investigation, StemExpress has endeavored to cooperate with the Majority Staff to provide timely and thorough responses to the Select Panel's myriad inquiries. Within days of receiving your first request for information just before Christmas 2015, StemExpress produced hundreds of pages of materials that were previously produced to the

House Energy & Commerce Committee, House Oversight & Government Reform Committee, and Senate Judiciary Committee. StemExpress subsequently continued to produce hundreds of pages of additional materials and respond to questions from the Majority Staff via several teleconferences. To date, StemExpress has nearly 900 pages of materials in response to the Select Panel's various inquiries, including the production of accounting reports and other work product that efficiently provided the Select Panel with certain categories of information that would otherwise have required more work for the Majority staff.

Despite StemExpress's consistent desire to cooperate with the Majority's ever-shifting demands, the Select Panel has now issued a total of three subpoenas to StemExpress and its Chief Executive Officer. Additionally, at least one former StemExpress employee has received a deposition subpoena from the Select Panel. StemExpress has repeatedly offered up a current employee with extensive experience with fetal tissue procurement and pricing as a corporate witness pursuant to Fed. R. Civ. P. 30(b)(6). Most recently, StemExpress offered its outside auditor and accountant as a potential witness. Rather than depose *any* of these individuals, the Select Panel appears intent on driving a predetermined narrative that suits its ends. This is incredibly disappointing to our client as the ultimate harm is to research and scientific breakthroughs that StemExpress has supported since its inception in 2010.

In light of the foregoing information, we respectfully request that the Select Panel withdraw or amend the Majority's proposed exhibits. Alternatively, we propose that tomorrow's hearing be held in a closed door executive session.

If you have any questions about this correspondence, please do not hesitate to contact me at 202-756-8380.

Sincerely,

Amandeep S. Sidhu

cc (via email w/encl.):

Kerry W. Kircher, General Counsel, U.S. House of Representatives
March Bell, Select Panel Majority Staff Director
Heather Sawyer, Select Panel Minority Chief Counsel

EXHIBIT A

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES - CENTRAL DISTRICT

STEMEXPRESS, LLC, et al.,)
Plaintiffs,)
vs.) No. BC 589145
THE CENTER FOR MEDICAL PROGRESS,)
BIOMAX PROCUREMENT SERVICES,)
LLC, DAVID DALEIDEN (aka)
"ROBERT SARKIS"), DOES 1 (aka)
"SUSAN TENNENBAUM"), and DOES)
2 through 100, inclusive,)
Defendants.)

VIDEOTAPED DEPOSITION OF DAVID DALEIDEN
Los Angeles, California
Wednesday, December 30, 2015
Volume 1

Reported by:
WENDY S. SCHREIBER
CSR No. 3558
Job No. 2199490

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES - CENTRAL DISTRICT

STEMEXPRESS, LLC, et al.,)
Plaintiffs,)
vs.) No. BC 589145
THE CENTER FOR MEDICAL PROGRESS,)
BIOMAX PROCUREMENT SERVICES,)
LLC, DAVID DALEIDEN (aka)
"ROBERT SARKIS"), DOES 1 (aka)
"SUSAN TENNENBAUM"), and DOES)
2 through 100, inclusive,)
Defendants.)

Videotaped Deposition of DAVID DALEIDEN, Volume 1, taken at 2049 Century Park East, Suite 3800, Los Angeles, California, commencing at 9:55 A.M., Wednesday, December 30, 2015, and ending at 6:41 P.M., before WENDY S. SCHREIBER, Certified Shorthand Reporter No. 3558.

APPEARANCES OF COUNSEL:

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DEPOSITION EXHIBITS
DAVID DALEIDEN

DEPOSITION EXHIBITS (CONTINUED)
DAVID DALEIDEN

PREVIOUSLY-MARKED EXHIBITS

LOS ANGELES, CALIFORNIA; DECEMBER 30, 2015
9:55 A.M. 09:44:51
09:57:53

VIDEO OPERATOR: Good morning. We are on 09:54:47
the record. The time is 9:55 a.m. The date today 09:55:10
is December 30th, 2015. 09:55:15
This is the video-recorded deposition of 09:55:18
David Daleiden. My name is David West, here with 09:55:22
our court reporter, Wendy Schreiber. We are here 09:55:25
from Veritext Legal Solutions at the request of 09:55:28
counsel for Plaintiff. 09:55:30
The deposition is being held at 2049 Century 09:55:30
Park East, 38th Floor, Los Angeles, California. 09:55:35
Case entitled StemExpress, LLC, et al., versus the 09:55:39
Center for Medical Progress, et al., Case No. 09:55:44
BC 589145. 09:55:47
Please note that audio and video recording 09:55:50
will take place unless all parties agree to go off 09:55:53
the record. Microphones are sensitive and may pick 09:55:55
up whispers, private conversations as well as 09:56:00
cellular interference. 09:56:02
I'm not authorized to administer an oath. 09:56:02
I'm not related to any party in this action, nor am 09:56:05
I financially interested in the outcome in any way. 09:56:07
If there are any objections to proceeding, 09:56:10

please state them at the time of your appearance. 09:56:12
Beginning with the noticing attorney, please state 09:56:15
your appearances. 09:56:17
MR. WEIR: Charles Weir of McDermott, Will & 09:56:19
Emery, for Plaintiffs. 09:56:21
MR. JONES: Gregory Jones, McDermott, Will & 09:56:22
Emery, for Plaintiffs. 09:56:25
MR. LiMANDRI: Charles LiMandri with the 09:56:25
Freedom of Conscience Defense Fund for the 09:56:28
Defendants. 09:56:28
MR. JONNA: Paul Jonna with the Freedom of 09:56:31
Conscience Defense Fund for the Defendants. 09:56:32
VIDEO OPERATOR: Thank you. The court 09:56:33
reporter may now swear in the witness and we will 09:56:35
proceed. 09:56:37

DAVID DALEIDEN,
having been first placed under oath, testified as
follows:

EXAMINATION

BY MR. WEIR:
Q. Good morning, Mr. Daleiden. 09:56:48
A. Good morning. 09:56:49
Q. How are you? 09:56:49

MR. WEIR: Do you have the order handy, Greg?
MR. LiMANDRI: I may be in the presence of recordings and then --
BY MR. WEIR:
Q. Did Holly O'Donnell ever -- I'll withdraw the question.
Did Holly O'Donnell ever tell you that she had a nondisclosure agreement with StemExpress?
A. No, she did not.
Q. Have you ever in your investigation of companies in the abortion industry seen a situation where they did have a nondisclosure agreement?
A. Can you clarify who you mean by "they"?
Q. The companies you were investigating in the abortion industry.
A. It still seems like a really broad question. Can you make that a little more specific for me? I don't totally understand.
Q. Do you know that there are -- that employees of companies in the abortion industry or fetal tissue industry that it is common for them to sign nondisclosure agreements?
MR. LiMANDRI: Objection: assumes facts not in evidence and beyond the scope of the discovery

order.
If you're comfortable answering, you can but I don't think you're required to.
THE WITNESS: Yeah, I don't -- I don't think it's necessarily common. I've encountered it in some situations but I've also not encountered it in some situations. I mean, part of why I asked you to clarify the question is because -- is because while I've seen confidentiality agreements and nondisclosure agreements present in some situations, they're not present in every situation. And so -- and so I've -- you know, so I wasn't sure exactly are you -- if you're just referring to, you know, NDAs between employers and employees or between potential business partners or -- there's lots of different situations.
BY MR. WEIR:
Q. Well, let's start with the employer/employee.
A. I -- I mean, like I said, I don't remember Holly ever telling me that she had a nondisclosure agreement or confidentiality agreement with StemExpress. The first that I ever knew of that was when I was browsing through all of the documents that she had given me after the fact and I saw a --

I saw what appeared to be some confidentiality portion incorporated into an employment contract.
Q. Those were the hard-copy documents?
A. I believe so.
Q. Okay. All right. So then -- was -- I think you might have said this before but the -- I'm getting tired, too. Was -- you had a log-in for Holly's e-mail?
A. Holly gave me her user name and password.
Q. That's what I was going to ask. It was password protected, correct?
A. I believe that's correct.
Q. Okay. All right. Let me check my notes. Let's go off the record. With any luck we will be done.
VIDEO OPERATOR: Off the record 6:15.
(Recess taken.)
VIDEO OPERATOR: On the record 6:18.
BY MR. WEIR:
Q. How did StemExpress first get on your radar?
A. StemExpress first got on my radar in 2011. It was the summer of 2011 and -- and a friend of mine was applying for -- or was looking for jobs in community pregnancy centers on the Internet, on Craig's List in Sacramento, and she -- and she

discovered a Craig's List ad for StemExpress for procurement technicians that talked about needing -- because I think she was doing searches for -- search terms like "abortion," "pregnancy center," "clinic worker," stuff like that and she found this -- this Craig's List ad for StemExpress procurement technicians saying that they were hiring procurement techs to work in Planned Parenthood clinics and work in abortion clinics to harvest pregnancy tissue.
And so she took a screen shot of that, forwarded it to me. And at that time I was already aware -- I had been aware for about a year of Advanced Bioscience Resources. I don't think I knew the connection between StemExpress and ABR and between Cate Dyer and ABR at that time but -- you know, but ABR had been interesting to me for about a year at that point since 2010 because -- you know, because I knew that they were one of the -- they were this really interesting, shadowy, reclusive fetal tissue procurement company. But then StemExpress was even more interesting in 2011 because not only, you know, were they in the same business but they were an explicitly for-profit company.
Q. Did you start investigating them immediately?

A. I -- in a certain sense, yeah, I began -- I definitely began researching them. 06:20:24 06:20:31

Q. All right. I have no further questions. 06:20:37

MR. LiMANDRI: Okay. I have no questions. 06:20:45

MR. WEIR: You have no questions? 06:20:48

MR. LiMANDRI: No. 06:20:49

MR. WEIR: Okay. Why don't we go with the same stipulations as yesterday if that's okay with you? 06:20:50 06:20:56 06:20:59

MR. LiMANDRI: Fine, that's good. 06:20:59

MR. WEIR: And then let's go off the record and talk about -- well, let's go off the record. 06:21:01 06:21:03

MR. LiMANDRI: Okay. 06:21:08

VIDEO OPERATOR: Off the record 6:21. 06:21:09

(Recess taken.) 06:41:01

VIDEO OPERATOR: The time is 6:41. We are back on the record. This will conclude today's testimony given by David Daleiden. The total number of media used was four. They will be retained by Veritext Legal Solutions. We are off the record at 6:41. 06:41:01 06:41:09 06:41:10 06:41:12 06:41:15 06:41:17

(TIME NOTED: 6:41 P.M.)

I, the undersigned, a Certified Shorthand Reporter of the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were administered an oath; that a record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; that the foregoing transcript is a true record of the testimony given.

Further, that if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript [ ] was [ ] was not requested.

I further certify I am neither financially interested in the action nor a relative or employee of any attorney or any party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: January 4, 2016

WENDY S. SCHREIBER, CSR No. 3558

I, DAVID DALEIDEN, do hereby declare under penalty of perjury that I have read the foregoing transcript; that I have made any corrections as appear noted, in ink, initialed by me, or attached hereto; that my testimony as contained herein, as corrected, is true and correct.

EXECUTED this _____, 20____, at _____, California.

_____

DAVID DALEIDEN

California Code of Civil Procedure

Article 5. Transcript or Recording

Section 2025.520

(a) If the deposition testimony is stenographically recorded, the deposition officer shall send written notice to the deponent and to all parties attending the deposition when the Original transcript of the testimony for each session of the deposition is available for reading, correcting, and signing, unless the deponent and the attending parties agree on the record that the reading, correcting, and signing of the transcript of the testimony will be waived or that the reading, correcting, and signing of a transcript of the testimony will take place after the entire deposition has been concluded or at some other specific time.

(b) For 30 days following each notice under subdivision (a), unless the attending parties and the deponent agree on the record or otherwise in writing to a longer or shorter time period, the deponent may change the form or the substance of the answer to a question, and may either approve the transcript of the deposition by signing it, or

refuse to approve the transcript by not signing it.

(c) Alternatively, within this same period, the deponent may change the form or the substance of the answer to any question and may approve or refuse to approve the transcript by means of a letter to the deposition officer signed by the deponent which is mailed by certified or registered mail with return receipt requested. A copy of that letter shall be sent by first-class mail to all parties attending the deposition.

(d) For good cause shown, the court may shorten the 30-day period for making changes, approving, or refusing to approve the transcript.

(e) The deposition officer shall indicate on the original of the transcript, if the deponent has not already done so at the office of the deposition officer, any action taken by the deponent and indicate on the original of the transcript, the deponent's approval of, or failure or refusal to approve, the transcript. The deposition officer shall also notify in writing the parties attending the deposition of any changes which the deponent timely made in person.

(f) If the deponent fails or refuses to approve the transcript within the allotted period, the

deposition shall be given the same effect as though it had been approved, subject to any changes timely made by the deponent.

(g) Notwithstanding subdivision (f), on a seasonable motion to suppress the deposition, accompanied by a meet and confer declaration under Section 2016.040, the court may determine that the reasons given for the failure or refusal to approve the transcript require rejection of the deposition in whole or in part.

(h) The court shall impose a monetary sanction under Chapter 7 (commencing with Section 2023.010) against any party, person, or attorney who unsuccessfully makes or opposes a motion to suppress a deposition under this section, unless the court finds that the one subject to the sanction acted with substantial justification or that other circumstances make the imposition of the sanction unjust.

DISCLAIMER: THE FOREGOING CIVIL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF SEPTEMBER 1, 2014. PLEASE REFER TO THE APPLICABLE STATE RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

EXHIBIT B

United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE
EASTERN DISTRICT of CALIFORNIA

U.S. Attorneys » Eastern District of California » News

Department of Justice

U.S. Attorney's Office

Eastern District of California

FOR IMMEDIATE RELEASE Tuesday, April 19, 2016

Washington Man Pleads Guilty to Sending Death Threats

SACRAMENTO, Calif. — Scott Anthony Orton, 57, of Puyallup, Washington, pleaded guilty today to transmitting interstate threats, United States Attorney Benjamin B. Wagner announced.

According to court documents, Orton posted several threatening statements on a popular news website in which he expressed his intent to travel to Placerville, California to kill an officer of the Placerville-based company, Stem Express LLC. On July 16, 2015, among other threats, Orton wrote, "The management of StemExpress should be taken by force and killed in the streets today. Kill StemExpress employees. I'll pay you for it." Orton also identified the target of his threats by name, and wrote "I'll pay ten grand to whomever beats me to [the target]."

"Terrorizing others through threats of violence, whether communicated in person or through media websites, is cruel, dangerous and disruptive, and is also a federal crime," said U.S. Attorney Wagner. "As Mr. Orton now knows, those who seek to terrorize others online will be identified and prosecuted."

This case is the product of an investigation by the Federal Bureau of Investigation. Assistant United States Attorney Brian A. Fogerty is prosecuting the case.

Orton is scheduled to be sentenced by United States District Judge John A. Mendez on August 2, 2016. Orton faces a maximum statutory penalty of five years in prison and a $250,000 fine. The actual sentence, however, will be determined at the discretion of the court after consideration of any applicable statutory factors and the Federal Sentencing Guidelines, which take into account a number of variables.

2:15-cr-233-JAM

USAO - California, Eastern

Updated April 19, 2016

March 9, 2000

VIA FACSIMILE

The Honorable Thomas Bliley
United States House of Representatives
Chairman, Committee on Commerce
Room 2125
Rayburn House Office Building
Washington, D.C. 20515-6115

Re: Anatomic Gift Foundation

Dear Representative Bliley:

As you know, the Anatomic Gift Foundation (AGF) has voluntarily complied with your requests and fully cooperated with your investigation. AGF has promptly provided you with all of the information you have requested and has even allowed your staff to tour AGF's offices and interview AGF's founder and executive director.

We were shocked by the information 20/20 presented last night on Dr. Miles Jones. We are concerned because we understand that Dr. Jones will likely not be attending the hearing today. He will therefore not be able to answer the serious charges of possible unlawful activity that the 20/20 investigation uncovered. We are, of course, unable to answer any questions related to Dr. Jones and Opening Lines, Inc.

Although AGF will continue to cooperate with your investigation, we will not be present at the hearing today. When we spoke with your assistant, Mr. Brent Del Monte, on several different occasions, he assured us that the invitation to AGF's acting president, Mr. James Bardsley, was just that – an invitation. Mr. Del Monte recognized that while Mr. Bardsley was welcome to attend the hearing, he was not subpoenaed and could decline the invitation if he chose. We told him that Mr. Bardsley's inclination at that time was to attend, and if that decision changed, we would inform you.

Bliley letter 03 09 2000

As promised, we are now advising you that Mr. Bardsley has elected not to attend the hearing. We believe that his appearance at the hearing is inadvisable for the following reasons: (1) AGF and its researchers have received serious threats (including the attached letter from the Army of God); (2) Dr. Jones is not likely to appear, and thus no one will be present to address the serious charges raised against him; (3) the National Institutes of Health will not appear; and (4) as a result, the only witnesses who will appear are a disgruntled former AGF employee who is a paid spy of an anti-abortion group, as well as his partner in a business that competes with AGF.

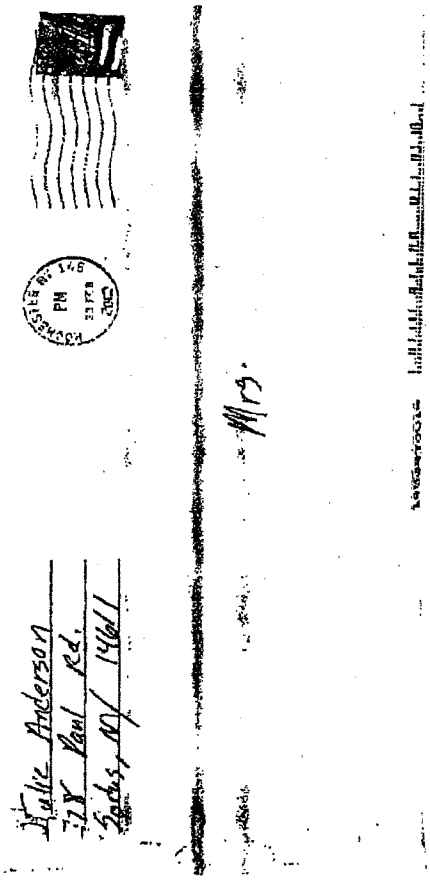
If you have any questions or would like further information from AGF, please call me or Joyce Pollack. You can also call Fay Clayton, who will return to the country on March 13.

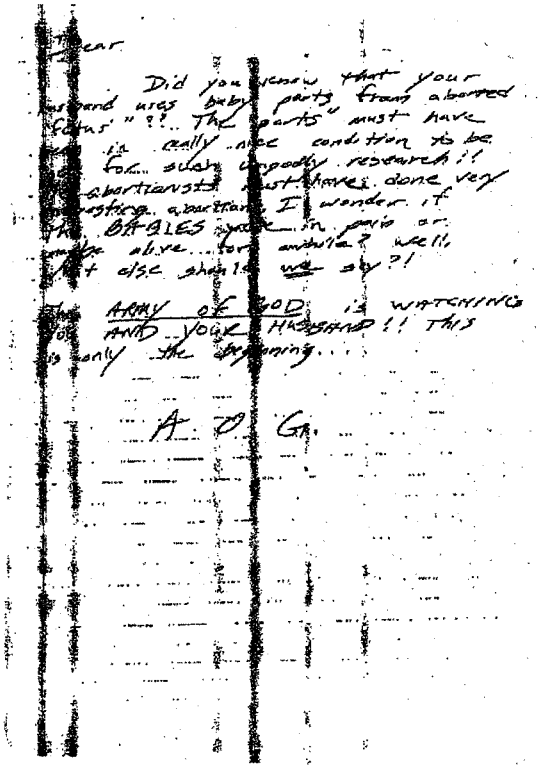
Respectfully,

Robert S. Michaels

Enclosure

49





Dear

Did you know that your husband uses baby parts from aborted fetus" ?! The parts" must have [illegible] condition to be [illegible] for... satanic ungodly research !! abortionists must have done very [illegible] abortion I wonder if the BAGELS you ate in paris or [illegible] above... for [illegible] ? well, [illegible] else should we say ?!

ARMY OF GOD is WATCHING AND your HUSBAND !! THIS only the beginning...

A. O. G.

the illegal sale of fetal tissue, in direct contravention of both medical ethics and Federal law.

Dr. Jones' statements were incriminating, to say the least, and he must be investigated by Federal authorities immediately.

I was almost as shocked, frankly, when I learned that, despite the majority's apparent knowledge of these facts since last November, no one has made a formal request to the Department of Justice to investigate Dr. Jones and his company.

Last November, my colleague from Colorado introduced a resolution condemning the illegal sale of fetal tissue and calling on this committee to hold a hearing, which I agreed with. So here we are today, almost 5 months later.

During all of this time, despite the horrific nature of the allegations against Dr. Jones and his company, no one has made a formal attempt to stop him, his business practices, or his company.

So what are we really up to here? Are we trying to stop an operator who is likely engaging in criminal activity, or is there a larger agenda?

Frankly, because of our shock after watching the ABC news program last night, my Democratic colleagues and I have sent the Department of Justice a letter requesting that an investigation begin immediately. Mr. Chairman, I would like to submit that for the record.

Mr. BILIRAKIS. Without objection, that will be the case.

Ms. DEGETTE. Thank you.

[The information referred to follows:]

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON COMMERCE
March 9, 2000

The Honorable JANET RENO
Attorney General
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530

The Honorable LOUIS FREEH
Director
Federal Bureau of Investigation
J. Edgar Hoover Building
935 Pennsylvania Avenue, S.W.
Washington, D.C. 20535

DEAR ATTORNEY GENERAL RENO AND DIRECTOR FREEH: Last night on the ABC News show "20/20", allegations were made that Opening Lines, a company that provides fetal tissue to researchers, was illegally profiting from the sale of this tissue by charging researchers a fee that includes more than Opening Lines' cost of providing the tissue.

Section 498B of the Public Health Service Act (42 U.S.C. 289g-2) states that it is a felony to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if this transfer affects interstate commerce. Valuable consideration does not include "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

Although allegations of obtaining illegal consideration for human fetal tissue by Opening Lines have been made by various parties for many months, it is our understanding that none of those making the allegations have ever referred this matter and their documentation or other evidence of criminal activity to the Justice Department for investigation.

Therefore, by this letter, we are requesting that the Justice Department and the Federal Bureau of Investigation conduct a full investigation of Opening Lines, its

principals and its current and former employees to determine if violations of Section 498B have occurred, and take ate enforcement action.

Sincerely,

JOHN D. DINGELL
Ranking Member, Committee on Commerce
SHERROD BROWN
Ranking Member, Subcommittee on Health and Environment
RON KLINK
Ranking Member, Subcommittee on Oversight and Investigations
HENRY A. WAXMAN
Member, Subcommittee on Health and Environment
DIANA DEGETTE
Member, Subcommittee on Health and Environment
BART STUPAK
Member, Subcommittee on Health and Environment
FRED UPTON
Member, Subcommittee on Health and Environment

Ms. DEGETTE. Dr. Miles Jones made very incriminating statements during a hidden camera interview on the program that indicates he may have profited from the illegal sale of fetal tissue. The authorities must investigate these statements.

I also just saw a letter that the chairman showed me from the Department of Justice to Mr. Upton. Apparently, Mr. Upton had contacted the Justice Department and was sent a letter, which I would also ask unanimous consent to include in the record, that they are reviewing the information obtained by 20/20.

[The information referred to follows:]

U.S. DEPARTMENT OF JUSTICE
OFFICE OF LEGISLATIVE AFFAIRS
March 9, 2000

The Honorable FRED UPTON
U.S. House of Representatives
Washington, DC 20515

DEAR REPRESENTATIVE UPTON: This responds to your telephone conversation this morning with Deputy Attorney General Eric Holder and your subsequent letter regarding the Department's efforts in enforcing the ban on the sale of fetal tissue for profit, especially in light of the information obtained by 20/20 on this issue, and your request to open an investigation on this matter.

As you know, recently there have been many troubling but unsubstantiated allegations in the media regarding the sale of fetal tissue for profit. However, based upon a preliminary review of our records, it appears that the Department has not received any information meeting our standards for triggering a formal investigation that fetal tissue has been sold for a profit. We are still reviewing our records for receipt of information. Further, three weeks ago, the National Institutes of Health and the Department of Health and Human Services informed the Department that they also had not received information of this kind. In addition, a 1997 study conducted by the General Accounting Office failed to turn up any reported violations of the ban by federally funded researchers covered by the study. *See* GAO, NIH-Funded Research: Therapeutic Human Fetal Tissue Transplantation Projects Meet Federal Requirements 3 (1997).

We are currently reviewing the information obtained by 20/20 to determine whether specific allegations raised by 20/20 warrant the opening of an investigation by the Department or a referral to another agency for investigation.

In the event that the Department receives specific information that a violation of federal law has occurred, we will investigate the matter to determine if there is sufficient evidence to support a prosecution or, where appropriate, refer the information to the proper agency for investigation.

Please do not hesitate to contact my office if we can be of further assistance.

Sincerely,

ROBERT RABEN
Assistant Attorney General

Back to previous page

[redacted]

document 1 of 1

Fetal Tissue Hearing Thrown Into Chaos

Zolt, Stacey. **Roll Call** [Washington, D.C] 13 Mar 2000: 1.

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Abstract

The House Commerce subcommittee on health and environment hearing was slated to deal with illegal underground traffic of fetal tissue, which had apparently been exposed on ABC's "20/20" Wednesday night. But Democrats trumped Republicans by pulling the rug out from under witness Dean Alberty.

Alberty appeared in a video on fetal tissue sales produced by Life Dynamics, an anti-abortion group, which was used by the committee for research. But committee Democrats obtained a deposition in which Alberty contradicted statements he made on the video and used the materials to back him into a corner during the hearing.

When Rep. Henry Waxman (D-Calif.) questioned Alberty on the discrepancies between the Life Dynamics video and his affidavit, Alberty said, "I would go by the affidavit, when I was under oath I told the truth. Anything I said on the video when I was not under oath, that is a different story."

Full Text

Democrats and Republicans were left pointing fingers over who was to blame for Thursday's botched hearing on fetal tissue sales after the panel's star witness left with his credibility in tatters.

The House Commerce subcommittee on health and environment hearing was slated to deal with illegal underground traffic of fetal tissue, which had apparently been exposed on ABC's "20/20" Wednesday night. But Democrats trumped Republicans by pulling the rug out from under witness Dean Alberty.

Alberty appeared in a video on fetal tissue sales produced by Life Dynamics, an anti-abortion group, which was used by the committee for research. But committee Democrats obtained a deposition in which Alberty contradicted statements he made on the video and used the materials to back him into a corner during the hearing.

When Rep. Henry Waxman (D-Calif.) questioned Alberty on the discrepancies between the Life Dynamics video and his affidavit, Alberty said, "I would go by the affidavit, when I was under oath I told the truth. Anything I said on the video when I was not under oath, that is a different story."

"There was a very loud gasp in the room," said Waxman Chief of Staff Phil Schiliro. "What he has said has been the basis for this whole investigation."

"In the videotape he talked about clinic doctors killing viable fetuses, but in his sworn deposition he said he didn't have an understanding of whether a fetus was alive or not," Waxman said.

Democrats believe that, while the alleged fetal tissue sales should be investigated, Republicans' entire basis for holding the hearing dissolved when the videotape was revealed to be false.

"I have never witnessed a witness whose credibility fell apart so rapidly," Waxman observed.

Republicans also took their shots at the discredited witness.

Rep. Jim Greenwood (R-Pa.) asked Alberty about a portion of the video featuring a "woman" wearing a green dress and long brown wig speaking in a digitized voice about the alleged fetal tissue sales.

"I said, 'Mr. Alberty, was that you?'" Greenwood recalled in an interview, adding that Alberty confirmed it was him wearing a wig. The Republican then asked if he was also wearing a dress. "He said, 'I don't recall.'"

"I think I'd remember if I were wearing a dress,"Greenwood retorted.

The exchange, according to Members and staff who were present, set the tone for a humorous - although embarrassing - demonstration of incomplete research by committee staff.

Now Republicans are seeking to turn the tables on Democrats, arguing that the only reason they appeared unprepared was because Democratic staffers withheld Alberty's deposition.

Commerce Committee spokesman Steve Schmidt said the panel staff could not interview Alberty prior to the hearing because he was under a gag order. Schmidt said the staff requested a copy of his deposition from the Anatomical Gift Foundation, but was refused.

Democratic committee staff, however, had obtained a copy of the deposition, and Republicans allege that Democrats did not give the majority staff a copy until Thursday.

"That seems to be the case that the deposition was not provided to Commerce Committee staff until 9:30 [Thursday morning] when it appears they might have had it for up to two weeks," Greenwood said.

"Which raises the question: Are the Democrats acting as defense counsel for the Anatomical Gift Foundation?" Schmidt said. "Had the Democrats shared with us the information, we would have been happy to excuse him as a witness," he said.

Meanwhile, Democrats claim Republicans had the affidavit first, a fact that also illustrated the discrepancies.

"Clearly we agree that Alberty's testimony left his credibility in shatters," Schmidt conceded. "He's clearly a liar and clearly Life Dynamics' ... credibility is also in shatters."

"This Life Dynamics group duped '20/20' and they duped the Congress," Waxman said. "It appears that they and all the other groups that they're aligned with went to the House leadership and demanded they hold this hearing."

The Republicans' other main witness was Miles Jones, the Missouri doctor who was allegedly running the business and was the subject of the "20/20" investigation.

Jones did not comply with the committee's subpoena and the panel voted unanimously to hold Jones in contempt of Congress.

Republicans now want to investigate Jones and the Anatomical Gift Foundation and find out for certain when Democrats obtained the deposition.

Schmidt said the hearing was investigative and worthwhile. "It was a first step looking at this issue. We saw evidence pretty clearly that the Democrats will go to all lengths possible to try and prevent this from going forward."

Democrats deny they're trying to block the investigation.

"It's a legitimate subject for inquiry," said a Democratic Commerce Committee spokesman. "If in fact these practices are being carried out then it's a subject for the law enforcement community. It is even more important a subject for serious committee inquiry. This was a slipshod, amateurish, half-baked, incompetent investigation."

"I went into this hearing with some concern as to whether they had some real evidence of abuse and whether ... there was a political agenda at work," Waxman said. "But I do think it's legitimate for our subcommittee to have oversight on this issue."

Waxman - along with Reps. John Dingell (D-Mich.), Sherrod Brown (D- Ohio), Ron Klink (D-Pa.), Diana DeGette (D-Colo.), Bart Stupak (D- Mich.) and Fred Upton (R-Mich.) - signed a letter asking the Justice Department and the FBI to investigate Jones' company, Opening Lines.

While Upton agrees that Alberty's credibility was "destroyed," he still believes the committee should pursue Jones' business.

"Based on what I saw [on '20/20'], I believe it would be a pretty airtight case against him," Upton said. "I would hope that the law can be enforced."

Upton called Deputy Attorney General Eric Holder Thursday morning to discuss the issue, and later received a reply indicating the Justice Department was willing to look into the evidence.

"20/20" Chief Correspondent Chris Wallace said he stands by the story, despite Alberty's testimony. "He said under oath that everything he told '20/20' was the truth."

"We were well aware that Mr. Alberty carried some baggage, that he was paid by a right-to-life group ... but we believe that parts of his story were true and we believe that because we were able to verify them with other sources," Wallace said.

"The bottom line is that we absolutely stand by every point made in our stories," Wallace said.

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Details

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March 16, 2000

NEWS

Bilirakis Left in Dark About Witness Problem

Before Explosive Fetal Tissue Hearing, Staff Didn't Tell Subcommittee Chairman About Conflicting Statements

By Stacey Zolt

Several GOP Members on the Commerce subcommittee on health and environment are appalled at the committee majority staff's failure to share a vital affidavit with the subcommittee chairman prior to last week's hearing on illegal fetal tissue sales.

Health Chairman Mike Bilirakis (R-Fla.) went into the hearing completely blind to the fact that the statements key witness Dean Alberty made in a Life Dynamics video circulated among Members contradicted statements Alberty made under oath in a deposition and affidavit conducted by an outside group.

Commerce Committee staffers were unable to depose Alberty themselves because he was restricted by a gag order.

Bilirakis was not told about the contradiction, which wound up wreaking havoc on last Thursday's subcommittee hearing, even though GOP and Democratic sources say the full committee majority staff had the affidavit at least one week before the hearing.

"He was just as surprised as everyone at the subpoenaed witness' statements," said Todd Tuten, Bilirakis' chief of staff. "Those are documents that neither my boss or his personal staff had access to prior to the hearing so we were not aware of the controversies in Mr. Alberty's public and written statements."

Alberty was subpoenaed by the majority based on his videotaped statements to Life Dynamics, a pro-life group, of witnessing illegal fetal tissue sales.

But he said in the affidavit that he has "no personal knowledge of any instances in which an employer of mine charged any fees or received any compensation for retrieving fetal tissue in

violation of any of these laws."

Steve Schmidt, spokesman for the full committee's majority staff, insisted that GOP aides for Commerce Chairman Tom Billey (R-Va.) did not have the affidavit until the morning of the hearing when they exchanged documents with the minority side.

"We had not seen the affidavit until that time," said Schmidt. "We, again, were unable to depose this witness [or] talk to this witness because he was under a gag order."

Even if the committee staff did not receive the affidavit until majority and minority counsel exchanged documents at 9:30 a.m. Thursday, one Republican aide to a Commerce member said that was more than ample time to notify Bilirakis of the discrepancy before the afternoon hearing.

"Anybody with a third-grade education would have brought that affidavit directly to Chairman Billey and Chairman Bilirakis," the aide said. "They never would have gone forward and made such a mockery out of such a highly respected committee."

Schmidt said the committee staff was just doing its job.

"As is custom here, we read documents before we would give them to the subcommittee chairman,"Schmidt said. "We were in the process of doing that and Mr. Bilirakis is not usually responsive to receiving documents that have not already been gone through by committee staff."

But, Tuten noted, "I think a review of the affidavit would lead you to the conclusion that Mr. Alberty had contradicted himself at least to some extent. And it raised considerable concerns not just for Chairman Bilirakis, but also for Republican subcommittee members who questioned the credibility of Mr. Alberty."

Democrats dispute Schmidt's account, claiming that they received the affidavit from Republicans.

"We got the affidavit from [Republicans] at least one week before the hearing," said Dennis Fitzgibbons, Commerce Committee minority staff spokesman.

Now, GOP sources said, Republican Members are working privately to solve the affidavit mystery and decide whether personnel action is necessary for the committee staff responsible for failing to reveal the evidence to Bilirakis.

An aide to a GOP Member on the subcommittee said Members were not only "disappointed in how it was handled and shocked at the outcome," but also confused as to what would motivate the Republican staff to deliberately keep the Members in the dark.

"I would say that was almost committee staff malpractice," the GOP aide said. "Knowing that our full committee staff had the affidavit, one wonders why they brought him in front of the committee to contradict himself. Frankly, I'm baffled."

In addition to Bilirakis, Rep. Fred Upton (R-Mich.) also had no idea that Alberty was not credible, according to spokesman Mike Waldron.

"He was shocked when that affidavit was presented at the committee hearing. My boss was shocked that he didn't know it existed and wasn't told about it," Waldron said. "He's concerned that Members on the majority side did not have the information going into the hearing that had disclosed the whole picture."

At a GOP staff briefing the day before the hearing, one aide present said many staffers raised questions about Alberty's credibility. Even without access to the affidavit, they felt the Life Dynamics video was questionable because of its low production quality.

"They were very prickly about it," the aide said. "There were several staffers who smelled a rat, especially those who saw the video."

Schmidt said no one questioned Alberty's credibility at that time.

"No one expressed any reservations because at the time the only people in possession of any evidence or documents that would question his credibility were the Democrats who chose not to share that with the majority staff,"he said.

Indeed, Democratic subcommittee members went into the hearing fully aware that Alberty was not credible and planned to prove the contradictions. The minority staff said it received Alberty's deposition from the Anatomical Gift Foundation and received the affidavit from the majority staff.

Rep. Henry Waxman (D-Calif.), for example, had enough information prior to the hearing to ask Alberty detailed questions on the discrepancies between the video and the affidavit, leading Alberty to admit he lied on the video.

"Republicans were just as much in the hot seat as Democrats," said a GOP aide familiar with the hearing. "If they read the affidavit, there was enough in that written document to convict the witness."

The way the committee staff handled the situation, the aide said, "didn't serve any member of the subcommittee well, including the chairman."

United States General Accounting Office
Washington, DC 20548

October 4, 2000

The Honorable Arlen Specter
Chairman
The Honorable Tom Harkin
Ranking Minority Member
Subcommittee on Labor, Health and Human
Services, and Education
Committee on Appropriations
United States Senate

The Honorable Bob Smith
United States Senate

Subject: Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research

Human fetal tissue is used in basic and preclinical biomedical research to advance knowledge of basic biological processes and improve research involving potential therapeutic approaches. It is also used in therapeutic transplantation or clinical research that involves the transplantation of human fetal tissue into patients for the cure or amelioration of diseases and disorders. The study, analysis, or use of human fetal tissue in biomedical research is considered by many medical researchers to offer promise for treatment of disorders and diseases such as Parkinson's disease, Alzheimer's disease, and diabetes.

You requested that we study the involvement of federal agencies under the jurisdiction of the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education in the acquisition of human fetal tissue for biomedical research. You specifically asked us to provide information on (1) which federal agencies under the Subcommittee's jurisdiction sponsor biomedical research using human fetal tissue, (2) the number of human fetal tissue samples acquired annually, (3) the number of central human fetal tissue supply organizations receiving federal funds, (4) the costs associated with acquiring human fetal tissue, (5) how researchers select and monitor human fetal tissue suppliers, (6) the extent to which federal human fetal tissue acquisition policies adhere to federal law, and (7) how federal agencies ensure that federally funded researchers comply with human fetal tissue law.

To address these questions, we interviewed officials from the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH), organizations that supply human fetal tissue for research, and selected institutional review boards that are responsible for the oversight of specific federally funded biomedical research

grants involving human fetal tissue. To gather information about the amount, sources, and costs of human fetal tissue used in biomedical research, we conducted a survey of NIH funded principal investigators for extramural and intramural research using human fetal tissue in fiscal years 1997, 1998, and 1999. Finally, we reviewed the laws, regulations, and policies relevant to human fetal tissue. We restricted our analysis to research projects that directly received human fetal tissue.[1] We carried out our work between July and September 2000 in accordance with generally accepted government auditing standards.

In brief, HHS officials reported that NIH is the only federal agency under the Labor, HHS, and Education Subcommittee's jurisdiction that sponsors research using human fetal tissue. On the basis of information supplied to us by NIH, we estimate that NIH awarded approximately $17.0 million for 103 research grants using human fetal tissue in fiscal year 1999. Principal investigators who responded to our survey acquired 12,116 human fetal tissue samples in fiscal years 1997 through 1999 for use in NIH-sponsored research. NIH funded three central human fetal tissue suppliers to provide human fetal tissue to biomedical researchers in fiscal year 1999. The costs of acquiring human fetal tissue were generally low. In fiscal year 1999, 49 percent of the principal investigators in our survey received human fetal tissue without paying an acquisition fee. Among those who did pay an acquisition fee, the average fee per sample was $80 in fiscal year 1999. The median number of tissue samples received by principal investigators in fiscal year 1999 was 26. In fiscal year 1999, 62 percent of principal investigators received human fetal tissue from central fetal tissue supply organizations, 31 percent from academic medical center hospitals, and 30 percent from health clinics or physicians' offices.[2] The principal investigators identified quality of the tissue supplier and a supplier's compliance with relevant regulations as the primary criteria for selecting their human fetal tissue suppliers. We found that federal human fetal tissue procurement policies and guidance are consistent with federal law. Review boards that are established at each institution performing HHS-funded biomedical research have the primary responsibility for ensuring that the procedures for acquiring human fetal tissue comply with federal, state, and local laws. The Office for Human Research Protections (OHRP) is the HHS entity that oversees the ongoing review practices of these institutional review boards.

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[1]This definition excludes (1) research involving human cord blood, placenta, amniotic fluid, and chorionic villi; (2) research involving derivatives of human fetal tissue such as human fetal cell cultures or human fetal cell lines; (3) studies involving a collection of existing human fetal tissue; and (4) pathology studies or autopsies.

[2]Sum of percentages is greater than 100 because some principal investigators had more than one supplier.

BACKGROUND AND METHODOLOGY

The NIH Revitalization Act of 1993 (P.L. 103-43) added two provisions to the Public Health Service Act regarding the acquisition and use of human fetal tissue.[3] The NIH Revitalization Act[4] prohibits a person from knowingly acquiring or transferring human fetal tissue for valuable consideration if the transfer affects interstate commerce. The statute defines "valuable consideration" as excluding reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. For therapeutic transplantation research, the NIH Revitalization Act requires written statements by the donor, the physician who obtained the tissue, and the researcher receiving the tissue to ensure that the provisions of the law are met. It further requires that all applicable state and local laws must be followed.[5]

Because we found no central source of information about the amount of human fetal tissue used for research or the number of human fetal tissue suppliers, we conducted a survey of principal investigators for all NIH-funded extramural and intramural research NIH reported to us as possibly using human fetal tissue for fiscal years 1997, 1998, and 1999. In the survey, we asked the principal investigators to identify (1) the number and type of entities they selected to be human fetal tissue suppliers, (2) the amount of tissue they received, (3) the number of shipments or acquisitions they received, and (4) the direct and indirect costs associated with human fetal tissue acquisition. We also asked principal investigators to identify the relevant oversight bodies at their institution, to describe the policies that exist at their institution regarding research using human fetal tissue, and to explain how their institution ensures compliance with federal, state, and local laws. We sent the survey instrument to all 160 of the investigators identified for us by NIH as having a research grant that may have involved the use of human fetal tissue for fiscal years 1997, 1998, and 1999. The survey was returned by 151 of the principal investigators, for a response rate of 94 percent. Of those respondents, 93 acquired fetal tissue for their research and completed the entire survey form, 47 told us that their research did not use human fetal tissue or that they did not acquire human fetal tissue in fiscal years 1997, 1998, and 1999, and 11 told us that they did not directly acquire human fetal tissue but used tissue acquired by another researcher included in our survey.[6]

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[3]Prior to the enactment of the NIH Revitalization Act, the National Organ and Transplantation Act of 1988 (P.L. 100-607) expanded the definition of "human organ" in the Public Health Service Act (42 U.S.C. section 274e) to include human fetal organs and tissue. This act thus prohibits the transfer of human organs, including human fetal tissue, for valuable consideration for use in human therapeutic transplantation.

[4]Section 112 of the NIH Revitalization Act, adding section 498B of the Public Health Service Act (42 U.S.C. section 289g-1).

[5]For a fuller description of this provision, see section 111 of the NIH Revitalization Act, adding section 498A of the Public Health Service Act, 42 U.S.C. section 298g-1.

[6]One hundred nineteen of the principal investigators received NIH grants in fiscal year 1999 (the remainder received funds only in fiscal years 1997 or 1998). For those with fiscal year 1999 grants the response rate was 97 percent; 68 acquired human fetal tissue in fiscal year 1999, 39 reported that they

FEDERALLY FUNDED BIOMEDICAL RESEARCH USING HUMAN FETAL TISSUE

HHS officials told us that NIH is the only federal agency under the Labor, HHS, and Education Appropriations bill that sponsors biomedical research using human fetal tissue. Separately, the Centers for Disease Control and Prevention told us that it does not conduct research using human fetal tissue. On the basis of information supplied to us by NIH, we estimate that NIH awarded to our survey respondents approximately $17.0 million for 103 research projects that used human fetal tissue in fiscal year 1999.[7] The researchers who responded to our survey collectively received $12.3 million in funding for extramural research at universities and research institutions, $3.2 million in funding for NIH intramural research, and $1.5 million for central human fetal tissue supply organizations.

NUMBER AND SOURCES OF TISSUE SAMPLES ACQUIRED

The NIH-sponsored biomedical researchers who responded to our survey acquired an average of roughly 4,000 samples of human fetal tissue in each year from fiscal years 1997 to 1999 (see table 1). We defined a tissue sample as a separate amount of tissue, or a single piece of tissue, in one vial. In fiscal year 1999, researchers received 4,147 samples in 1,878 shipments or acquisitions. The median number of tissue samples received by principal investigators in fiscal year 1999 was 26.

Table 1: Human Fetal Tissue Samples Acquired, by Fiscal Year

Fiscal year	Number of fetal tissue samples
1997	3,676
1998	4,293
1999	4,147
Total	**12,116**

The principal investigators we surveyed received human fetal tissue most often from central tissue suppliers. Among principal investigators who identified their sources for human fetal tissue in fiscal year 1999, 62 percent received human fetal tissue from central tissue suppliers, 31 percent from academic medical center hospitals, and 30

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did not use human fetal tissue in their research or that they did not receive human fetal tissue in fiscal year 1999, and 9 reported that they did not directly acquire human fetal tissue but used tissue acquired by another researcher we surveyed. In addition to data from the 68 researchers who acquired tissue in fiscal year 1999, our analyses for that year also included data from 10 researchers with NIH grants for only fiscal years 1997 and/or 1998 who told us that they also acquired human fetal tissue in fiscal year 1999.

[7]This total was calculated by summing the grant funding amounts we received from NIH for survey respondents who told us that their research used human fetal tissue in fiscal year 1999. This total probably is slightly understated, however, because some of the researchers who did not respond to our survey may have used human fetal tissue.

percent from health clinics.[8] Fifty four percent of all of the human fetal tissue samples received by the NIH-sponsored researchers we surveyed came from central tissue suppliers in fiscal year 1999. Likewise, 34 percent of the tissue samples came from health clinics and 10 percent from academic medical centers.

CENTRAL TISSUE SUPPLY ORGANIZATIONS

NIH sponsors three central human fetal tissue supply organizations. The Birth Defects Laboratory at the University of Washington is funded by NIH for the sole purpose of providing human fetal tissue to federally funded biomedical researchers. While most of the laboratory's funds are provided by NIH, it also charges researchers a small fee for the human fetal tissue samples it collects, prepares, and distributes. The laboratory distributed 2,869 human fetal tissue samples and collected $52,035 in fees directly from researchers in fiscal year 1999. NIH provided a grant award of $346,743 to maintain the laboratory's capabilities in fiscal year 1999. NIH also funds the Brain and Tissue Banks for Developmental Disorders at the University of Maryland and the University of Miami School of Medicine/Children's Hospital of Orange County primarily to serve as suppliers of human nonfetal tissue for the study of developmental disorders, but both banks also supply a relatively small amount of human fetal tissue to biomedical researchers. In fiscal year 1999, NIH funds totaled $563,823 for the University of Maryland Bank and $574,643 for the University of Miami Bank. The University of Maryland Bank provided 195 human fetal tissue samples to investigators in fiscal year 1999, and the University of Miami Bank provided approximately 40 samples between March 1 and August 31, 1999.

In addition, some researchers obtained human fetal tissue from private, nonprofit central tissue supply organizations that did not directly receive federal funds. In their responses to our survey, the principal investigators who received tissue from these sources most frequently obtained tissue from Advanced Bioscience Resources, Incorporated (Alameda, California), and the Albert Einstein College of Medicine Human Fetal Tissue Repository (New York, New York).

COSTS OF ACQUIRING HUMAN FETAL TISSUE

The direct acquisition fees for human fetal tissue were low. In fiscal year 1999, 49 percent of the respondents to our survey did not pay any acquisition fees for the human fetal tissue they received. Among those who paid acquisition fees in fiscal year 1999, investigators reported an average fee of $80 per human fetal tissue sample, with a minimum fee of $2 and a maximum fee of $214. In addition, tissue acquisition fees varied substantially among the different sources identified in our survey. Only one of the researchers who received human fetal tissue from academic medical centers paid an acquisition fee ($12). More than four-fifths of the researchers who received tissue from health clinics paid no fee. The fees per sample of human fetal tissue from health clinics ranged from $2 to $75, with an average of $22. In contrast,

[8]Sum of percentages is greater than 100 because some principal investigators had more than one supplier. Three percent of these respondents did not categorize their tissue source.

78 percent of the researchers receiving human fetal tissue from a central tissue supplier paid an acquisition fee--those fees ranged from $5 to $214 per sample, with investigators paying an average fee of $96.[9]

Second, some of the principal investigators who completed our survey had additional expenses for transporting, processing, preserving, storing, and ensuring the quality of human fetal tissue specimens, even if they paid nothing to acquire the tissue. For all of the principal investigators who responded to our survey, total expenditures for acquiring human fetal tissue in fiscal year 1999 totaled approximately $359,000, including both tissue acquisition fees and these other expenses (see table 2). This total includes about $142,000 in acquisition fees, $80,000 in shipping and transportation costs, and $135,000 in other internal laboratory costs for processing, preserving, storing, and ensuring quality.[10]

Table 2: Total Costs Related to Acquiring Human Fetal Tissue, Fiscal Year 1999

Cost category	Number of investigators incurring cost	Average annual cost per investigator	Total for all investigators
Acquisition fee	40 (51%)	$3,554	$142,144
Shipping and transportation costs	42 (54%)	$1,914	$80,405
Other direct costs	9 (11%)[a]	$176	$1,580
Internal costs	13 (17%)[b]	$10,350	$134,550
Total			**$358,679**

[a]Two respondents who said that they had other direct costs but did not provide a cost figure are not included.
[b]Seven respondents who said that they had internal costs but did not provide a cost figure are not included.

CRITERIA FOR SELECTING HUMAN FETAL TISSUE SUPPLIERS

In response to an open-ended question on our survey, principal investigators reported that quality of tissue and compliance with federal regulations were their primary criteria for choosing a human fetal tissue supplier. Overall, 55 percent of the respondents who received human fetal tissue in fiscal year 1999 told us that they

[9]Twelve percent of researchers who obtained human fetal tissue from central supply organizations paid no fee. Ten percent of researchers who identified central supply organizations as the entity that supplied their tissue did not tell us whether or not they paid an acquisition fee.

[10]Shipping and transportation costs include any costs associated with transporting tissue samples from the supplier to the researcher by any means, including by personal delivery or commercial shipping company, and shipping supplies such as sample containers or sterile media provided by the researcher. Other direct costs include renting space at a supplier's facility, in-kind services or donations of staff time or supplies to the tissue supplier, and any other financial considerations to the tissue supplier. Internal costs are any costs researchers may have incurred as a result of acquiring fetal tissue that they would not have otherwise, such as equipment for storing the tissue.

selected a tissue supplier on the basis of the qualifications and reliability of its staff, its reputation for high-quality work, or other reasons indicating a preference for a high-quality supplier. Forty-four percent of these 1999 respondents told us that the supplier's compliance with federal and state laws, or its nonprofit status, was an important reason for their selection. Thirty-seven percent told us that the location of the tissue supplier was important (21 percent told us that the tissue supplier was part of their institution). Fewer respondents (29 percent) selected a tissue supplier simply because appropriate human fetal tissue was available there. Finally, 9 percent of those who received human fetal tissue in fiscal year 1999 told us that the low cost of the tissue was a factor in their selection of a supplier.

HUMAN FETAL TISSUE POLICIES AND GUIDANCE

The NIH Revitalization Act of 1993 places limits on the procurement of human fetal tissue. The statute bars anyone from knowingly acquiring, receiving, or transferring human fetal tissue for valuable consideration if the transfer affects interstate commerce. For therapeutic transplantation research, it further bars directed donations of human fetal tissue and payment of valuable consideration for costs associated with terminating a pregnancy. Each of these prohibitions carries criminal penalties, including fines and imprisonment. Because these provisions do not require implementing regulations,[11] NIH addresses the importance it attaches to these statutory requirements and the criminal penalties that the prohibitions carry through guidance to its grantee researchers. In its forthcoming policy statement on "Research on Human Fetal Tissue," NIH emphasizes that "the scientific and ethical challenges associated with research utilizing human fetal tissues make it imperative that researchers and their institutions be clearly aware of and in compliance with federal requirements," especially those that carry criminal penalties.

INSTITUTIONAL REVIEW BOARDS

Except for research conducted at its own facilities, NIH does not directly oversee the conduct of research using human fetal tissue. Instead, under the regulations regarding the protection of human subjects, institutional review boards oversee HHS-funded research using human fetal tissue.[12] These review boards are required at all institutions conducting HHS-supported research. The boards are responsible for approving research proposals before studies begin and for periodically reviewing studies after they are under way to ensure compliance with relevant regulations for the protection of human subjects. OHRP is the HHS entity responsible for ensuring that the institutional review boards are conducting the appropriate reviews of HHS-funded research using human fetal tissue. Before grant funds are distributed, the grantee institution submits an "assurance" to OHRP. The assurance is a written

[11]In addition, although not directly addressing the procurement of human fetal tissue, NIH regulations specifically require that "activities" involving these materials must be in accordance with any applicable state or local laws (45 C.F.R. section 46.210).

[12]Almost all of our survey respondents identified the institutional review board at their institution as the body responsible for oversight of their research.

statement of an institution's requirements for its institutional review board and human-subject protections. If the institution receives only one grant from HHS, a single project assurance is submitted to OHRP. If the institution receives many HHS grants, a multiple project assurance is submitted. In the assurance, the institution states that the research will be conducted in compliance with applicable federal, state, and local laws. Institutions are required to renew multiple project assurances every 5 years after an initial period of 3 years. Continuing reviews of the HHS-funded projects are conducted annually by the institutional review boards.[13]

NIH's Office of Intramural Research periodically reviews each intramural investigator using fetal tissue to confirm that they are complying with the relevant requirements.

AGENCY COMMENTS

NIH and OHRP officials reviewed a draft this report. They provided technical comments, which we incorporated where appropriate.

We will make copies of this letter available to those who are interested on request.

Major contributors to this report were Martin T. Gahart, Emily J. Rowe, Jenny C. Chen, Lisanne Bradley, and Stefanie Weldon. Please contact me at (202) 512-7119 if you have any questions.

Janet Heinrich
Director, Health Care - Public Health Issues

(201089)

[13]Our review did not evaluate the effectiveness of institutional review board oversight. We previously reported that NIH-sponsored investigators conducting therapeutic human fetal tissue transplantation research were in compliance with federal laws and regulations. See *NIH-Funded Research: Therapeutic Human Fetal Tissue Transplantation Projects Meet Federal Requirements* (GAO/HEHS-97-61, Mar. 10, 1997).

SCICHECK · THE WIRE

Unspinning the Planned Parenthood Video

By Dave Levitan Posted on July 21, 2015

Several Republican presidential candidates have claimed that Planned Parenthood is "profiting" from abortions. But the full, unedited video they cite as evidence shows a Planned Parenthood executive repeatedly saying its clinics want to cover their costs, not make money, when donating fetal tissue from abortions for scientific research.

Four experts in the field of human tissue procurement told us the price range discussed in the video — $30 to $100 per patient — represents a reasonable fee. "There's no way there's a profit at that price," said Sherilyn J. Sawyer, the director of Harvard University and Brigham and Women's Hospital's "biorepository."

Republicans made their claims following the release of a secretly recorded video showing Deborah Nucatola, the senior director of medical services at Planned Parenthood, discussing the procurement of fetal tissues when conducting abortions. The edited video, released July 14 by an anti-abortion group called the Center for Medical Progress, leaves the impression that Nucatola is talking about Planned Parenthood affiliates making money from fetal tissue. But the edited video ignores other things Nucatola said that contradict that idea.

The Videos, Edited and Unedited

At one point in the unedited video (which was also released by the group), Nucatola says: "Affiliates are not looking to make money by doing this. They're looking to serve their patients and just make it not impact their bottom line."

Nucatola also says, "No one's going to see this as a money making thing." And at another point, she says, "Our goal, like I said, is to give patients the option without impacting our bottom line. The messaging is this should not be seen as a new revenue stream, because that's not what it is."

The footage was recorded secretly during a lunch meeting on July 25, 2014, between Nucatola and two people posing as employees of a company looking to procure fetal tissue for research purposes.

While eating a salad and drinking red wine, she casually discusses which tissues are valued by researchers and how to preserve those tissues while conducting abortions. Planned Parenthood President Cecile Richards has apologized for Nucatola's "tone" and manner of speaking, which House Speaker John Boehner condemned as "cavalier" in calling for a congressional investigation.

In the edited video, Nucatola says the cost for fetal tissue specimens was between $30 and $100, "depending on the facility and what's involved." She defined "specimen" as, "one case. One patient."

Republicans have focused on those comments, characterizing the practice as a way to profit off abortion:

> *Rick Perry, July 14: The video showing a Planned Parenthood employee selling the body parts of aborted children is a disturbing reminder of the organization's penchant for profiting off the tragedy of a destroyed human life.*
>
> ***Rand Paul, July 14:** ... a video showing [Planned Parenthood]'s top doctor describing how she performs late-term abortions to sell body parts for profit!*
>
> ***Carly Fiorina, July 14:** This latest news is tragic and outrageous. This isn't about "choice." It's about profiting on the death of the unborn while telling women it's about empowerment.*

Nucatola's comment, though, isn't evidence that Planned Parenthood or its affiliates are selling "body parts" or fetal tissue for profit. The full video shows that after Nucatola mentions the $30 to $100, she describes how those amounts would be reimbursement for expenses related to handling and transportation of the tissues. Nucatola talks about "space issues" and whether shipping would be involved.

We asked all three candidates listed above whether they believed the $30 to $100 per specimen amount constitutes making a "profit" from fetal tissue, and we did not receive specific answers to that question. The chief political strategist for Rand Paul's campaign, Doug Stafford, sent us the following statement in an email:

> ***Stafford, July 15:** Planned Parenthood and their supporters in the media are willing to say anything to defend their taxpayer funded abortions and profiteering from selling aborted fetuses. They want to argue about what week they kill a child or how much they do or do not profit? What's blatantly obvious is that Planned Parenthood is trying to distract from their extremist positions and immoral "business."*

We also asked experts in the use of human tissue for research about the potential for profit. Sherilyn J. Sawyer, the director of Harvard University and Brigham and Women's Hospital's "biorepository," told us that "there's no way there's a profit at that price." She continued in an email:

> ***Sawyer, July 20:** In reality, $30-100 probably constitutes a loss for [Planned Parenthood]. The costs associated with collection, processing, storage, and inventory and records management for specimens are very high. Most hospitals will provide tissue blocks from surgical procedures (ones no longer needed for clinical purposes, and without identity) for research, and cost recover for their time and effort in the*

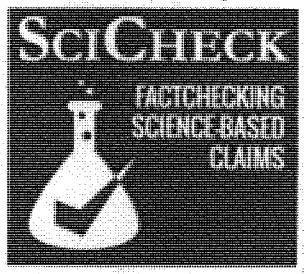
> *range of $100-500 per case/block. In the realm of tissues for research $30-100 is completely reasonable and normal fee.*

Jim Vaught, president of the International Society for Biological and Environmental Repositories and formerly the deputy director of the National Cancer Institute's Office of Biorepositories and Biospecimen Research, told us in an email that "$30 to $100 per sample is a reasonable charge for clinical operations to recover their costs for providing tissue." In fact, he said, the costs to a clinic are often much higher, but most operations that provide this kind of tissue have "no intention of fully recovering [their] costs, much less making a profit."

Carolyn Compton, the chief medical and science officer of Arizona State University's National Biomarkers Development Alliance and a former director of biorepositories and biospecimen research at the National Cancer Institute, agreed that this was "a modest price tag for cost recovery." Compton told us in an email: " 'Profit' is out of the question, in my mind. I would say that whoever opined about 'profit' knows very little about the effort and expense involved in providing human biospecimens for research purposes."

Nucatola does make one statement in the unedited video that suggests to critics that some clinics would be comfortable with a payment that was slightly more than their expenses for providing the tissue. "I think for affiliates, at the end of the day, they're a nonprofit, they just don't want to — they want to break even. And if they can do a little better than break even, and do so in a way that seems reasonable, they're happy to do that," Nucatola says.

But immediately after this statement, Nucatola goes on to say: "Really their bottom line is, they want to break even. Every penny they save is just pennies they give to another patient. To provide a service the patient wouldn't get." Planned Parenthood told us that she may have been referring to more general operations of the clinics.



Nucatola repeatedly talks about affiliates only wanting to provide a service to their patients, who elect to donate the tissue for medical research, and not having that service impact their bottom lines. She says that it's "not a new revenue stream the affiliates are looking at" and that "nobody should be 'selling' tissue. That's just not the goal here." She says some affiliates might donate the tissue for free.

Nucatola also discusses Planned Parenthood clinics' interactions with a tissue procurement company called StemExpress. The company's website says that partnering with StemExpress can be "financially profitable" for a clinic — a point that some conservative websites have singled out. But this also does not constitute evidence that Planned Parenthood is profiting in such a way.

StemExpress, which provides other types of tissue aside from fetal tissue, did not respond to our request for clarification on profitability. It did release a statement on its website expressing pride in its work to advance research and saying it complies "with all laws."

According to another tissue procurement company called Advanced Bioscience Resources, which has provided fetal tissues to researchers in a number of federally funded studies, the costs mentioned in the video are reasonable. Linda Tracy, ABR's president, told us in an email that "[i]t is difficult to pinpoint the exact cost of tissue acquisition due to the many variables involved," such as the location of the facility, the specific requests from researchers and any special handling that is required. She said, however, that "$30 to $100 is within a comparable range of what ABR pays for reimbursement of costs."

At one point in the video, Nucatola tells the "buyers" (the actors purporting to represent a fetal tissue procurement company are described as "buyers" in a transcript provided by the Center for Medical Progress) that affiliates wouldn't make decisions about whether to work with a tissue research organization based on money. "You could call them up and say, 'I'll pay you double the money,' and they're almost more inclined to say no, because it's going to look bad. ... To them, this is not a service they should be making money from, it's something they should be able to offer this to their patients, in a way that doesn't impact them."

She then suggests that these "buyers" might be able to compete with other companies by offering extra services, such as taking tissue the clinics would otherwise have to dispose of themselves.

In a statement on its website, Planned Parenthood defended its affiliates' practice of fetal tissue donation as "standard across the medical field":

> ***Planned Parenthood, July 14:*** *At several of our health centers, we help patients who want to donate tissue for scientific research, and we do this just like every other high-quality health care provider does — with full, appropriate consent from patients and under the highest ethical and legal standards. There is no financial benefit for tissue donation for either the patient or for Planned Parenthood. In some instances, actual costs, such as the cost to transport tissue to leading research centers, are reimbursed, which is standard across the medical field.*

Richards, the Planned Parenthood president, said in a video response to the controversy: "The allegation that Planned Parenthood profits in any way from tissue donation is not true."

On July 21, the Center for Medical Progress released a second, similar video, again featuring a discussion with a Planned Parenthood official in a restaurant. The numbers mentioned in the edited video are similar to what Nucatola said. The official, Mary Gatter, quotes a rate of $75 per specimen, and says she was thinking of saying $50. The discussion only reaches $100 because the "buyers" in the video mention higher prices. At one point, Gatter says that "we're not in this for the money," and later she reiterates that "money is not the important thing."

Though few studies of costs associated with fetal tissue acquisition are available, existing evidence does suggest the prices named in the video are in line with general practices. The National Institutes of Health conducts research with fetal tissue, and in the late 1990s, the Government Accountability Office (then known as the General Accounting Office) looked into the acquisition of such tissue, finding that the direct cost to researchers was "low." GAO said payments primarily went to "central tissue suppliers," as opposed to health clinics. In most

cases, GAO found that clinics did not charge researchers, but when they did, the cost ranged from $2 to $75. The report did not address how much clinics might have received from central tissue suppliers, which is more analogous to the situation presented in the video.

What Does the Law Say?

In a statement made to CNN, another presidential candidate, retired neurosurgeon Ben Carson, called the practice discussed in the video a "clear violation of federal law." The "sale" of organs, both adult and fetal, for transplantation is indeed illegal, but donation of tissue — both from aborted fetuses and from adults — is not. And payment for "reasonable" costs is also allowed under the law.

The video itself highlights a portion of title 42 of the U.S. code, which reads: "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce." The law does include fetal tissue in its definitions. It says that the term "valuable consideration" doesn't include "reasonable payments" for removal, transportation, preservation and other associated costs.

In 1993, a law pertaining to federally funded NIH research was enacted that allows donation of fetal tissue from induced abortions if certain criteria are met. These include that the woman donating is not aware of the recipients of the tissue, and that the abortion timing, procedures or method itself would not be altered for the sole purpose of obtaining the tissue.

The 1993 law also says that it is unlawful "for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." The law again excludes the types of costs Nucatola discussed in the video: "The term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

The American Medical Association echoes this in its ethical guidelines on the issue: "Fetal tissue is not provided in exchange for financial remuneration above that which is necessary to cover reasonable expenses."

Why Is Fetal Tissue Scientifically Useful?

Historically, the use of fetal tissue has produced some groundbreaking scientific discoveries. According to the American Society for Cell Biology, a nonprofit representing a large and varied group of scientists, "Fetal cells hold unique promise for biomedical research due to their ability to rapidly divide, grow, and adapt to new environments. This makes fetal tissue research relevant to a wide variety of diseases and medical conditions."

According to the Guttmacher Institute, a nonprofit focused on sexual and reproductive health, tissue from fetuses has been used since the 1930s for a variety of purposes. Perhaps most famously, the 1954 Nobel Prize in medicine was awarded to researchers who managed to grow polio vaccine in fetal kidney cell cultures.

In another example, Leonard Hayflick created a cell line from an aborted fetus in the early 1960s that has been used to create vaccines against measles, rubella, shingles and other diseases.

Paul Offit, director of the Vaccine Education Center at the Children's Hospital of Philadelphia, told the journal *Nature* in 2013 that "[t]hese cells from one fetus have no doubt saved the lives of millions of people."

In more recent years, however, the use of stem cells for therapeutic and research purposes has taken a more central role than fetal tissue. As Arthur Caplan, a bioethicist at New York University, told Buzzfeed News, "fetal cells are not a big deal in science anymore."

In spite of the waning interest, it remains legal to donate tissue from a legally aborted fetus, and for that tissue to be used for research purposes.

Editor's Note: SciCheck is made possible by a grant from the Stanton Foundation.

– Dave Levitan and Lori Robertson

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The NEW ENGLAND JOURNAL of MEDICINE

BRIEF REPORT

Zika Virus Associated with Microcephaly

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SUMMARY

A widespread epidemic of Zika virus (ZIKV) infection was reported in 2015 in South and Central America and the Caribbean. A major concern associated with this infection is the apparent increased incidence of microcephaly in fetuses born to mothers infected with ZIKV. In this report, we describe the case of an expectant mother who had a febrile illness with rash at the end of the first trimester of pregnancy while she was living in Brazil. Ultrasonography performed at 29 weeks of gestation revealed microcephaly with calcifications in the fetal brain and placenta. After the mother requested termination of the pregnancy, a fetal autopsy was performed. Micrencephaly (an abnormally small brain) was observed, with almost complete agyria, hydrocephalus, and multifocal dystrophic calcifications in the cortex and subcortical white matter, with associated cortical displacement and mild focal inflammation. ZIKV was found in the fetal brain tissue on reverse-transcriptase–polymerase-chain-reaction (RT-PCR) assay, with consistent findings on electron microscopy. The complete genome of ZIKV was recovered from the fetal brain.

ZIKV, AN EMERGING MOSQUITO-BORNE FLAVIVIRUS, WAS INITIALLY ISOlated from a rhesus monkey in the Zika forest in Uganda in 1947.[1] It is transmitted by various species of aedes mosquitoes. After the first human ZIKV infection, sporadic cases were reported in Southeast Asia and sub-Saharan Africa.[2] ZIKV was responsible for the outbreak in Yap Island of Micronesia in 2007 and for major epidemics in French Polynesia, New Caledonia, the Cook Islands, and Easter Island in 2013 and 2014.[3,4] In 2015, there was a dramatic increase in reports of ZIKV infection in the Americas. Brazil is the most affected country, with preliminary estimates of 440,000 to 1.3 million cases of autochthonous ZIKV infection reported through December 2015.[5]

The classic clinical picture of ZIKV infection resembles that of dengue fever and chikungunya and is manifested by fever, headache, arthralgia, myalgia, and maculopapular rash, a complex of symptoms that hampers differential diagnosis. Although the disease is self-limiting, cases of neurologic manifestations and the Guillain–Barré syndrome were described in French Polynesia and in Brazil during ZIKV epidemics.[5,6] Recent reports from the Ministry of Health of Brazil suggest that cases of microcephaly have increased by a factor of approximately 20 among newborns in the northeast region of the country, which indicates a possible association between ZIKV infection in pregnancy and fetal malformations.[5]

We present a case of vertical transmission of ZIKV in a woman who was prob-

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ably infected with ZIKV in northeastern Brazil at the end of the first trimester of pregnancy. Our discussion includes details of fetal imaging and pathological and virologic analyses.

CASE REPORT

In mid-October 2015, a 25-year-old previously healthy European woman came to the Department of Perinatology at the University Medical Center in Ljubljana, Slovenia, because of assumed fetal anomalies. Since December 2013, she had lived and worked as a volunteer in Natal, the capital of Rio Grande do Norte state. She had become pregnant at the end of February 2015. During the 13th week of gestation, she had become ill with high fever, which was followed by severe musculoskeletal and retroocular pain and an itching, generalized maculopapular rash. Since there was a ZIKV epidemic in the community, infection with the virus was suspected, but no virologic diagnostic testing was performed. Ultrasonography that was performed at 14 and 20 weeks of gestation showed normal fetal growth and anatomy.

The patient returned to Europe at 28 weeks of gestation. Ultrasonographic examination that was performed at 29 weeks of gestation showed the first signs of fetal anomalies, and she was referred to the Department of Perinatology. At that time, she also noticed reduced fetal movements. Ultrasonography that was performed at 32 weeks of gestation confirmed intrauterine growth retardation (estimated third percentile of fetal weight) with normal amniotic fluid, a placenta measuring 3.5 cm in thickness (normal size) with numerous calcifications, a head circumference below the second percentile for gestation (microcephaly), moderate ventriculomegaly, and a transcerebellar diameter below the second percentile. Brain structures were blurred, and there were numerous calcifications in various parts of the brain (Fig. 1A and 1B). There were no other obvious fetal structural abnormalities. Fetal, umbilical, and uterine blood flows were normal on Doppler ultrasonography.

The clinical presentation raised suspicion of fetal viral infection. Because of severe brain disease and microcephaly, the fetus was given a poor prognosis for neonatal health. The mother requested that the pregnancy be terminated, and the procedure was subsequently approved by national and hospital ethics committees. Medical termination of the pregnancy was performed at 32 weeks of gestation. At the delivery, the only morphologic anomaly was the prominent microcephaly. Genetic consultation that included a detailed maternal family history revealed no suspicion of genetic syndromes or diseases. An autopsy was performed, as is mandatory in all cases of termination of pregnancy. The mother provided written informed consent for the publication of this case report.

METHODS

AUTOPSY AND CENTRAL NERVOUS SYSTEM (CNS) EXAMINATION

An autopsy of the fetus and placenta was performed 3 days after termination of the pregnancy, with an extensive sampling of all organs, placenta, and umbilical cord. Samples were fixed in 10% buffered formalin and embedded in paraffin. Fresh tissue samples were collected for microbiologic investigations. Brain and spinal cord were fixed in 27% buffered formalin for 3 weeks, after which a neuropathological examination was performed with extensive sampling of the brain and spinal cord. Sections of all tissue samples were stained with hematoxylin and eosin. Immunostaining for glial fibrillary acid protein, neurofilament, human leukocyte antigen DR (HLA-DR), CD3 (to highlight T cells), and CD20 (to highlight B cells) was performed on representative CNS samples.

ELECTRON MICROSCOPY

Tissue was collected from formalin-fixed brain and underwent fixation in 1% osmium tetroxide and dehydration in increasing concentrations of ethanol. The sample was then embedded in Epon. Semithin sections (1.4 μm) were made, stained with Azur II, and analyzed by means of light microscopy. Ultrathin sections (60 nm) were stained with uranyl acetate and lead citrate. In addition, a small piece of brain (5 mm^3) was homogenized in buffer. The suspension was then cleared by low-speed centrifugation, and the obtained supernatant was ultracentrifuged directly onto an electron microscopic grid with the use of an Airfuge (Beckman Coulter). Negative staining was performed with 1% phosphotungstic

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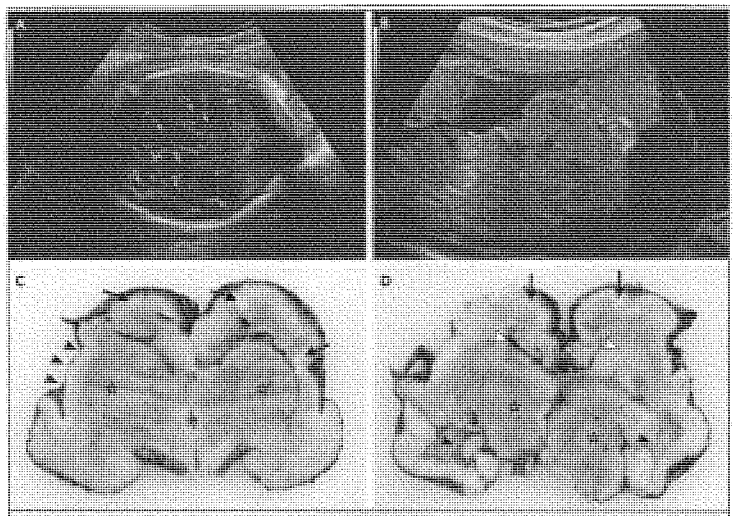

Figure 1. Prenatal Ultrasonographic Images and Photographs of Coronal Slices of Brain.

Panel A shows numerous calcifications in cortical parts of the brain (some marked with arrows) and the dilated occipital horn of the lateral ventricle (Vp, marked with a measurement bar) as seen on transverse ultrasonography. Panel B shows numerous calcifications in the placenta. Panel C shows subcortical cortical and subcortical white calcifications (arrows) and almost complete lack of gyration of the cortex. The basal ganglia are developed but poorly delineated (black arrowhead), and the sylvian fissures are widely open on both sides (arrowheads on the left). The third ventricle is not dilated (white arrowhead). Panel D shows dilated body of the lateral ventricles (white arrowheads; the left is collapsed). Temporal horns of the lateral ventricles (black arrowheads) are also dilated. The thalami (black asterisks) and the left hippocampus (white asterisk) are well developed, whereas the contralateral structure is not recognizable owing to autolysis.

acid. Imaging of the ultrathin sections and brain homogenate was performed with the use of a 120-kV JEM-1400Plus transmission electron microscope (JEOL).

INDIRECT IMMUNOFLUORESCENCE

Paraffin-embedded sections of the fetal brain tissue and brain tissue of an autopsied man as a negative control were incubated with serum obtained from the mother of the fetus (dilution, 1:10), followed by antihuman IgG antibodies labeled with fluorescein isothiocyanate (FITC) (dilution, 1:50). In addition, fetal brain tissue was incubated with a serum obtained from a healthy blood donor, as well as with FITC-labeled antihuman IgG antibodies only.

MICROBIOLOGIC INVESTIGATION

RNA was extracted from 10 mg of the placenta, lungs, heart, skin, spleen, thymus, liver, kidneys, and cerebral cortex with the use of a TRIzol Plus RNA purification kit (Thermo Fisher Scientific). Real-time RT-PCR for the detection of ZIKV RNA (NS5) and one-step RT-PCR for the detection of the envelope-protein coding region (360 bp) were performed as described previously.[7,8] In addition, next-generation sequencing was performed in samples of fetal brain tissue with the use of Ion Torrent (Thermo Fisher Scientific) and Geneious software, version 9.0.6. Reads from both runs were combined and mapped to the reference sequence (ZIKV MR766; LC002520) with the use of default measures. For phylogenetic analysis,

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complete-genome ZIKV sequences were used, and multiple sequence alignments (ClustalW) were performed. A neighbor-joining phylogenetic tree (GTR+G+I model) was constructed, with the use of the MEGA6 software system,[9] to show the phylogenetic relationships. The nucleotide sequence of ZIKV that was obtained in this study has been deposited in GenBank under accession number KU527068. A detailed description of the molecular methods is provided in the Supplementary Appendix, available with the full text of this article at NEJM.org. The results of comprehensive serologic analyses of maternal serum and a description of the molecular differential diagnostic procedures used with fetal tissue samples are provided in Tables S1 and S2 in the Supplementary Appendix. All the authors vouch for the completeness and accuracy of the data and analyses presented.

RESULTS

AUTOPSY AND NEUROPATHOLOGICAL FINDINGS

The fetal body weight was 1470 g (5th percentile), the length 42 cm (10th percentile), and the head circumference 26 cm (1st percentile). The only external anomaly that was noted was microcephaly. The placenta weighed 200 g, resulting in a placental–fetal weight ratio of 0.136 (<3rd percentile). Macroscopic examination of the CNS revealed micrencephaly with a whole-brain weight of 84 g (4 SD below average), widely open sylvian fissures, and a small cerebellum and brain stem. Almost complete agyria and internal hydrocephalus of the lateral ventricles were observed. There were numerous variable-sized calcifications in the cortex and subcortical white matter in the frontal, parietal, and occipital lobes. The subcortical nuclei were quite well developed (Fig. 1C and 1D). In spite of some autolysis, microscopic examination revealed appropriate cytoarchitecture of the fetal brain. The most prominent histopathological features were multifocal collections of filamentous, granular, and neuron-shaped calcifications in the cortex and subcortical white matter with focal involvement of the whole cortical ribbon, occasionally associated with cortical displacement (Fig. 2A and 2B). Diffuse astrogliosis was present with focal astrocytic outburst into the subarachnoid space, mostly on the convexity of the cerebral hemispheres (Fig. 2C). Activated microglial cells and some macrophages expressing HLA-DR were present throughout most of the cerebral gray and white matter (Fig. 2D). Scattered mild perivascular infiltrates composed of T cells and some B cells were present in the subcortical white matter (Fig. S1 in the Supplementary Appendix). The cerebellum, brain stem, and spinal cord showed neither inflammation nor dystrophic calcifications. The brain stem and spinal cord showed Wallerian degeneration of the long descending tracts, especially the lateral corticospinal tract, whereas ascending dorsal columns were well preserved (Fig. 2E). Indirect immunofluorescence revealed granular intracytoplasmic reaction in destroyed neuronal structures, which pointed to a possible location of the virus in neurons (Fig. 2F, and Fig. S1 in the Supplementary Appendix). Histologic examination of the placenta confirmed focal calcifications in villi and decidua, but no inflammation was found. There were no relevant pathological changes in other fetal organs or in the umbilical cord or fetal membranes. Fetal karyotyping with the use of microarray technology showed a normal 46XY (male) profile.

ELECTRON MICROSCOPY

Although analysis of the ultrathin sections of the brain showed poorly preserved brain tissue with ruptured and lysed cells, clusters of dense virus-like particles of approximately 50 nm in size were found in damaged cytoplasmic vesicles. Groups of enveloped structures with a bright interior were also detected. At the periphery of such groups, the remains of membranes could be seen. Negative staining of homogenized brain revealed spherical virus particles measuring 42 to 54 nm with morphologic characteristics consistent with viruses of the Flaviviridae family (Fig. 3).

MICROBIOLOGIC INVESTIGATION

Positive results for ZIKV were obtained on RT-PCR assay only in the fetal brain sample, where 6.5×10^7 viral RNA copies per milligram of tissue were detected. In addition, all autopsy samples were tested on PCR assay and were found to be negative for other flaviviruses (dengue virus, yellow fever virus, West Nile virus, and tick-borne encephalitis virus), along with chikungunya virus, lymphocytic choriomeningitis, cytomegalovirus, rubella virus, varicella–zoster virus, herpes simplex virus, parvovirus B19, enteroviruses, and

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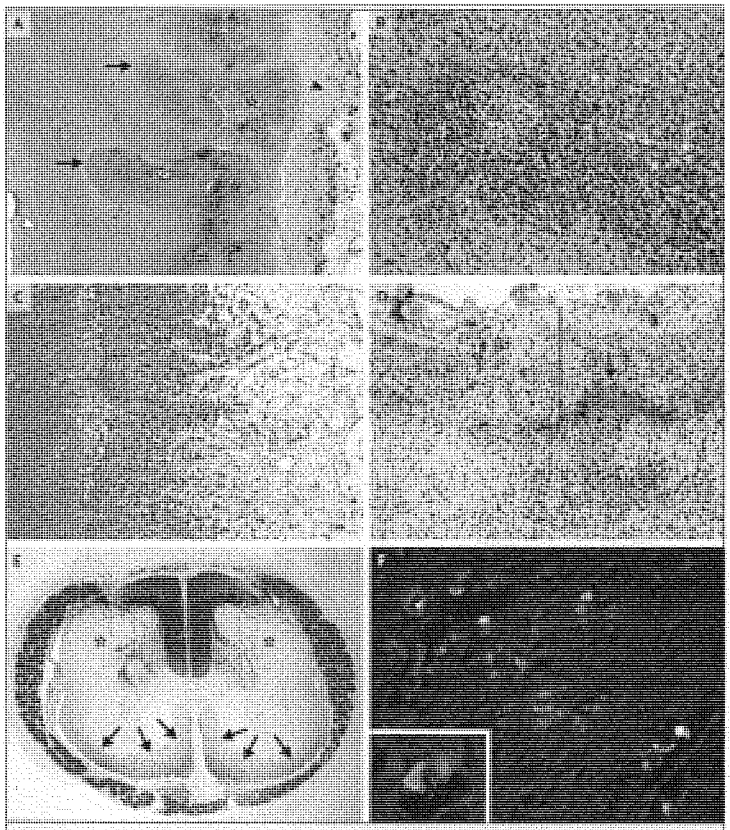

Figure 2. Microscopic Analysis of Brain Tissue.

Panel A shows thickened leptomeninges (black arrowhead) and irregular cortical and subcortical calcifications (asterisks) associated with cortical displacement (arrow), with preserved gyrencephalic cortex (white arrowhead); gyrencephaly is absent. Panel B shows higher magnification of calcifications with filamentous structures (arrow), possibly representing encrusted, damaged axons and dendrites, and oval and polygonal structures (arrowheads), possibly representing encrusted, damaged neuronal cell bodies. Periodic acid–Schiff staining in Panels A and B. Panel C shows immunohistochemical labeling of proliferated reactive astrocytes that extend into the subarachnoid space (asterisk) (glial fibrillary acid protein, clone 6F2 [Dako]). Panel D shows immunohistochemical labeling of numerous activated microglial cells and macrophages in the cortex (full thickness marked with a line) and subcortical white matter (lower part of the figure). Fibrinoid staining of the calcifications is present (arrow). Focal leptomeningeal infiltrates of macrophages are seen (arrowhead) (HLA-DR, clone TAL.1B5 [Dako]). Panel E shows noncalcified myelin and neuronal staining of tissue in a cross-section of the lumbar spinal cord with severe Wallerian degeneration of the lateral corticospinal tracts (black asterisks), moderate involvement of other descending tracts (arrows), and well-preserved ascending tracts in the dorsal columns (white asterisk) (myelin stain, clone LFB1 [Dako]). Panel F shows indirect immunofluorescence of fetal brain tissue, revealing a green granular intracytoplasmic reaction (see also inset). The yellow signals adjacent to the green granules indicate autofluorescence of lipofuscin, suggesting that viral particles are located in the cytoplasm of neurons.

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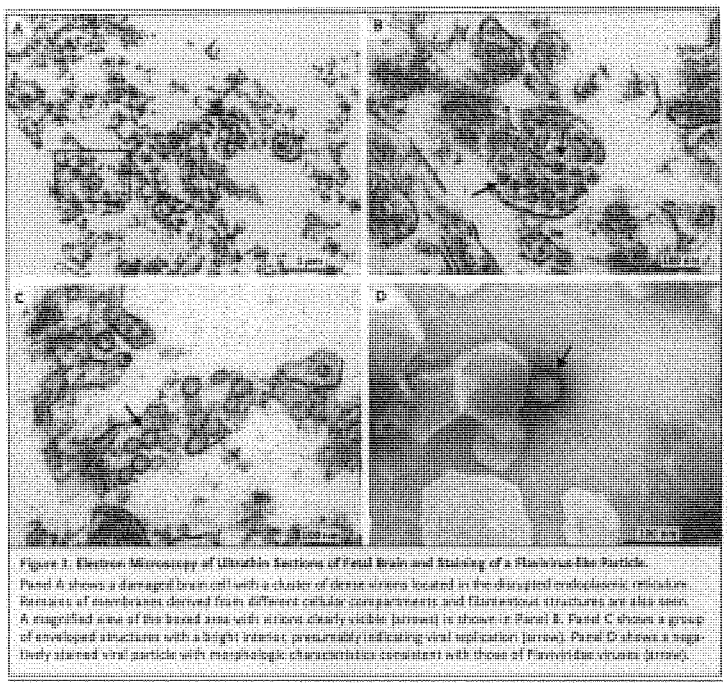

Figure 3. Electron Microscopy of Ultrathin Sections of Fetal Brain and Staining of a Flavivirus-like Particle.

Panel A shows a disrupted brain cell with a cluster of dense virions located in the disrupted endoplasmic reticulum. Remnants of membranes derived from different cellular compartments and fluorescent structures are also seen. A magnified area of the boxed area with virions clearly visible (arrows) is shown in Panel B. Panel C shows a group of enveloped structures with a bright interior, presumably indicating viral replication (arrow). Panel D shows a negatively stained viral particle with morphologic characteristics consistent with those of Flaviviridae viruses (arrow).

Toxoplasma gondii (Table S2 in the Supplementary Appendix).

A complete ZIKV genome sequence (10,808 nucelotides) was recovered from brain tissue. Phylogenetic analysis showed the highest identity (99.7%) with the ZIKV strain isolated from a patient from French Polynesia in 2013 (KJ776791) and ZIKV detected in Sao Paolo, Brazil, in 2015 (KU321639), followed by a strain isolated in Cambodia in 2010 (JN860885, with 98.3% identity) and with a strain from the outbreak in Micronesia in 2007 (EU545988, with 98% identity) (Fig. 4). In the ZIKV polyprotein, 23 polymorphisms were detected in comparison with the strain from Micronesia and 5 polymorphisms in comparison with the isolate from French Polynesia; three amino acid changes were found in the NS1 region (K940E, T1027A, and M1143V), one in the NS4B region (T2509I), and one in the FtsJ-like methyltransferase region (M2634V).

DISCUSSION

This case shows severe fetal brain injury associated with ZIKV infection with vertical transmission. Recently, ZIKV was found in amniotic fluid of two fetuses that were found to have microcephaly, which was consistent with intrauterine transmission of the virus.[10] Described cases are similar to the case presented here and were characterized by severely affected CNS and gross intrauterine growth retardation. Calcifications in the placenta and a low placental–fetal weight ratio,[11] which were seen in this case, indicate potential damage to the placenta by the virus. Among the few reports of teratogenic effects of

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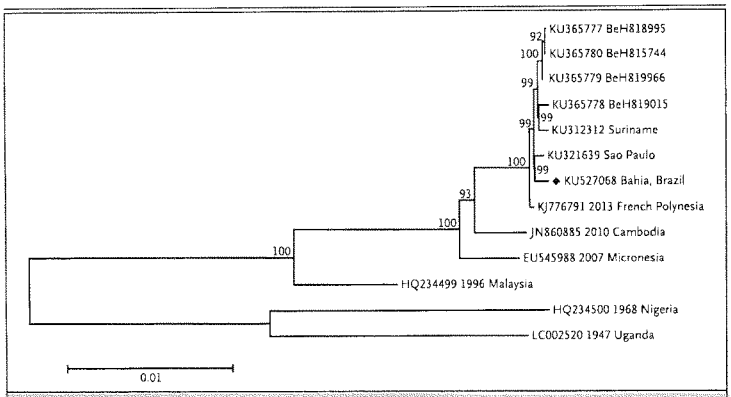

Figure 4. Phylogenetic Analysis of the Complete Genome of Zika Virus.

The evolutionary history was inferred by means of the neighbor-joining method under a GTR+G+I substitution model. The percentage of replicate trees in which the associated taxa clustered together in the bootstrap test (2000 replicates) is shown next to the branches. The GenBank accession number, year of isolation, and country of origin are indicated on the ZIKV branches for all strains except for those identified in 2015 and 2016. ZIKV strain Bahia, Brazil (KU527068), was obtained in this study. The complete genome sequence was recovered from fetal brain tissue. The 0.01 scale bar denotes the genetic distance in nucleotide substitutions per site.

flaviviruses, investigators described the brain and eyes as the main targets.[12,13] No presence of virus and no pathological changes were detected in any other fetal organs apart from the brain, which suggests a strong neurotropism of the virus.

The localization of immunofluorescence signal and the morphologic appearance of the calcifications, which resembled destroyed neuronal structures, indicate a possible location of the virus in neurons. The consequent damage might cause arrested development of the cerebral cortex at the embryonic age of approximately 20 weeks.[14] The mechanism involved in the neurotropism of ZIKV is currently not clear. The association between ZIKV infection and fetal brain anomalies was also noted by findings on electron microscopy that were consistent with ZIKV detection in the fetal brain. Dense particles consistent with ZIKV were seen in damaged endoplasmic reticulum. Groups of enveloped structures with a bright interior resembling the remains of replication complexes that are characteristic of flaviviruses[15,16] indicate viral replication in the brain. The findings on electron microscopy suggest a possible persistence of ZIKV in the fetal brain, possibly because of the immunologically secure milieu for the virus. The number of viral copies that were detected in the fetal brain were substantially higher than those reported in the serum obtained from adult ZIKV-infected patients[17] but similar to those reported in semen samples.[18]

The complete genome sequence of ZIKV that was recovered in this study is consistent with the observation that the present strain in Brazil has emerged from the Asian lineage.[19] The presence of two major amino acid substitutions positioned in nonstructural proteins NS1 and NS4B probably represents an accidental event or indicates a process of eventual adaptation of the virus to a new environment. Further research is needed to better understand the potential implications of these observations. It is likely that the rapid spread of ZIKV around the globe will be a strong impetus for collaborative research on the biologic properties of the virus, particularly since the risk of neurotropic and teratogenic virus infections places a high emotional and economic burden on society.

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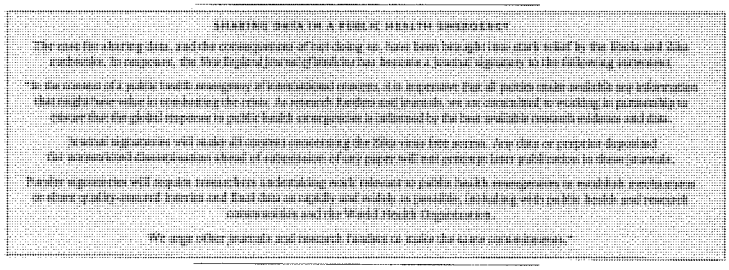

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(HTTP://WWW.LATIMES.COM/)

Over two days of hearing, Democrats questioned former fetal tissue technician Holly O'Donnell on her statements.

How anti-abortion activists used undercover Planned Parenthood videos to further a political cause

By JEREMY BRENINGSTALL, ELIZABETH D. HERMAN, PAIGE ST. JOHN (HTTP://WWW.LATIMES.COM/LA-BIO-PAIGE-ST-JOHN-STAFF.HTML)

MARCH 30, 2016

She was subdued and sympathetic on camera. Her recollections of collecting fetal tissue and body parts from abortion clinics in northern California lent emotional force to the anti-abortion videos that provoked a furor in Congress last summer.

In footage made public last July, Holly O'Donnell said she had been traumatized by her work for a fetal-tissue brokerage. She described feeling "pain...and death and eternity" and said she fainted the first time she touched the remains of an aborted fetus.

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Unreleased footage filed in a civil court case shows that O'Donnell's apparently spontaneous reflections were carefully rehearsed. David Daleiden, the anti-abortion activist who made the videos, is heard coaching O'Donnell through repeated takes, instructing her to repeat anecdotes, add details, speak "fluidly" and be "very natural."

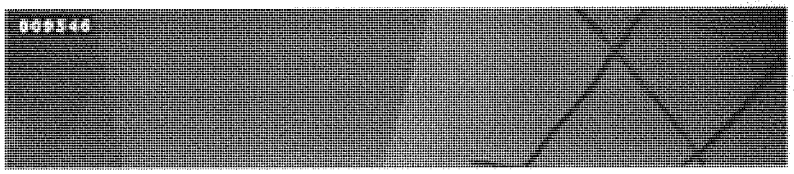
"Let's try it two more times," he told her at one point.

Later, O'Donnell protested: "I don't want to tell that story again. Please don't make me again, David."

For more than two years, Daleiden and a small circle of anti-abortion activists went undercover into meetings of abortion providers and women's health groups. With fake IDs and tiny hidden cameras, they sought to capture Planned Parenthood officials making inflammatory statements. O'Donnell cooperated with the filmmakers, offering an inside view of the fetal tissue trade.

"We are so good"

David Daleiden and Sandra Merritt discuss how abortion providers trust them so much they could enter a clinic to sift through "product of conception," the term used for an aborted fetus. (Center for Medical Progress / Los Angeles Superior Court)



The videos sparked numerous investigations into Planned Parenthood and efforts in Congress to strip the organization of its federal funding.

Now, Daleiden, head of the Irvine-based Center for Medical Progress, and his associates contend that they were acting as investigative journalists, seeking to expose illegal conduct. That is one of their defenses in lawsuits brought by Planned Parenthood and other groups, accusing them of fraud and invasion of privacy.

But unpublicized footage and court records show that the activists' methods were geared more toward political provocation than journalism.

The Times and the Investigative Reporting Program at UC Berkeley took a detailed look at published and unreleased video footage, sworn declarations, excerpts of recorded dialogue and other court records from the lawsuits against Daleiden.

The videos and court records show that Daleiden and his associates — posing as representatives of a fetal tissue brokerage — tried to loosen the tongues of abortion providers with alcohol.

In conversations, they tried to plant phrases such as "fully intact baby" and to elicit statements suggesting that fetuses were alive when their tissue and organs were harvested for use in medical research.

A comparison of raw footage and the videos he released shows that Daleiden edited out material that conflicted with his premise that Planned Parenthood-affiliated clinics profit from the sale of fetal tissue for research purposes.

Daleiden, asked for comment, said: "I think our methods are really credible." His lawyers have said Daleiden employed common tools of investigative reporting.

Abortion clinics can recoup costs they incur in supplying donated fetal tissue to medical researchers but they are not allowed to profit from the exchange.

Eight months after the release of the videos, investigations in a dozen states have found no wrongdoing by Planned Parenthood. Nevertheless, the organization apologized for callous remarks caught by Daleiden's cameras, and it has barred affiliated clinics from accepting even legal reimbursement for making fetal tissue available for research.

In January, a Houston grand jury that had been investigating the videos cleared Planned Parenthood and instead indicted Daleiden and fellow activist Sandra Merritt on felony charges of tampering with government records — using fake California driver's licenses to arrange meetings with Planned Parenthood officials in Houston. Through their lawyers, Daleiden and Merritt have said they will fight the charges.

Sandra Merritt arrives at the Harris County Criminal Courthouse in Houston in February. (Eric Kayne / Getty Images)

David Daleiden leaves the courtroom in Houston after turning himself in to authorities in February. (Bob Levey / AP)

In response to civil lawsuits filed by the National Abortion Federation (NAF) and StemExpress, a fetal-tissue brokerage in Northern California, Daleiden has asserted that because he was seeking to prevent murder, he had the right to break confidentiality agreements he signed to gain access to abortion meetings.

(Planned Parenthood has filed a separate civil fraud lawsuit against Daleiden.)

On Feb. 5, U.S. District Judge William Orrick in San Francisco issued an injunction requested by the NAF to keep more than 500 hours of Daleiden's unreleased footage under seal.

Orrick said the videos Daleiden has made public so far "have not been pieces of journalistic integrity, but misleadingly edited videos and unfounded assertions... of criminal misconduct."

Daleiden's "fraud" was so extensive and his videos so misleading that his still-unpublished recordings of private conversations do not warrant 1st Amendment protection as free speech, the judge said. In his order, Orrick used the words "fraud" or "fraudulently" 13 times in referring to Daleiden's methods.

Daleiden and his associates are appealing the injunction in a bid to unseal the tapes. Meanwhile, the case is headed to trial, with the NAF seeking unspecified damages for fraud, trespassing, invasion of privacy, racketeering and other alleged offenses.

Daleiden, 27, who graduated from Claremont McKenna College with a degree in government studies, has been involved in undercover operations against abortion clinics for years.

In sworn testimony, he said the objective of his most recent operation was to prove the fetal tissue trade encourages illegal abortion procedures.

In a memo to supporters, Daleiden said he wanted to generate "political pressure" on Planned Parenthood, focusing on "Congressional hearings/investigation and political consequences," such as new restrictions on abortion in the U.S.

As he and his associates prepped in hotel rooms before entering closed-door meetings of the NAF in San Francisco and Baltimore, Daleiden told the undercover activists to lead their "targets" into "saying something really, like, messed up — like 'Yeah, like, I'll give them, like, 'live' everything for you.'"

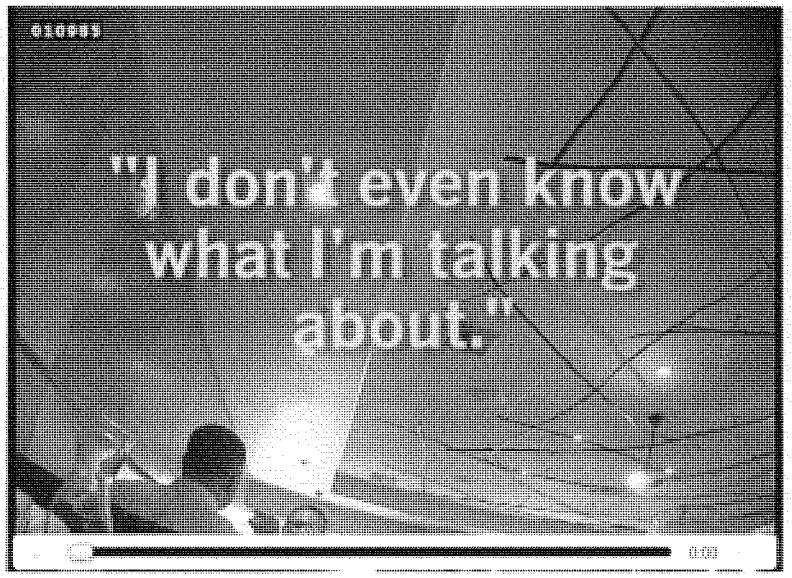
"If they say something like that, it would be cool," he said.

The activists were given key phrases to elicit from their targets. "Fully intact baby" was one.

Daleiden, in an interview, said he trained his associates to "build in a certain number of repetitions and redundancies, clarification, so it's absolutely clear what is going on to someone who's just like Joe Schmo off the street."

"We finished the whole bottle"

Daleiden sometimes recorded targets over drinks. At one meeting, the owner of a tissue brokerage refused the wine that was ordered and Daleiden's fellow activist, Sandra Merritt, says she drank most of the bottle. (Center for Medical Progress/Los Angeles Superior Court)



The undercover activists zeroed in on those they thought might be susceptible to alcohol. According to excerpts quoted in court records, Daleiden told Merritt at an NAF meeting that it "would be really good to talk tonight" with one doctor, "now that she's been drinking."

At another point, he proposed "a little chat" with a physician who had consumed "a little wine," and suggested that Merritt "invite her to lunch in the next two days. I think she's the one for our purposes."

Excerpts of recorded conversations cited in court records indicate that another effort to lead a target to drink was foiled when a tissue broker refused the wine Daleiden and Merritt ordered.

Merritt joked that she had consumed most of the bottle herself, and as they walked out of the restaurant, she said she was too inebriated to read a message on Daleiden's phone.

"I don't even know what I'm talking about. Oh, my God.... We finished the whole bottle, too!" she said. "Good thing you brought someone who can hold their liquor."

Repeated attempts to reach Merritt by phone and at her home were unsuccessful.

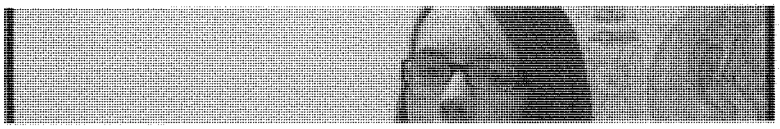
In the publicly released videos, Daleiden made extensive use of testimony from O'Donnell, a former technician for StemExpress.

Daleiden became aware of her through Facebook, and she met with him six times over two years, turning over boxes of StemExpress records and her company email password. Daleiden said in a deposition that he used the password to download company documents, including shipping invoices that identified researchers who bought tissue.

Unreleased footage shows that over the source of successive takes, Daleiden asked O'Donnell to repeat anecdotes or add details such as the gender of an aborted fetus and whether she "said goodbye" to a dissected fetal cadaver before placing it in a bio-hazard container.

"Yeah, I could say that"

Over two days of taping, Daleiden coached former fetal tissue technician Holly O'Donnell on her responses. At one point she asks: "How do you want me to say it?" (Center for Medical Progress / Los Angeles Superior Court)



"So you want to make it really dramatic?" she asked.

At one point, she laughed and said to Daleiden: "You're all like, 'Say it like this! Let me possess your body and I'll say it for you.'"

Daleiden protested that he was not coaching her, but as he asked O'Donnell to recount her experiences, her telling grew more dramatic and emotional.

In an early take, she says into the camera: "I got into the medical field because I wanted to help people, not steal fetal tissues."

On the third try, she says: "I got into the medical field to help people, not to steal dead baby parts and sell them."

Efforts to reach O'Donnell for comment for this article, by phone and by email, were unsuccessful.

Daleiden billed an edited version of O'Donnell's interviews as the "harrowing story of harvesting an intact brain from a late-term male fetus whose heart was still beating."

Outtakes show he edited out her statement that the fetus was dead before the brain tissue was removed — but included her saying that the heart was briefly restarted by being tapped.

Daleiden had her describe the case repeatedly. It was then that she said: "I don't want to tell that story again. Please don't make me again, David."

Daleiden replied: "That was very powerful. I think that's going to change the world."

Deborah VanDerhei (left) and Planned Parenthood Federation of America executive Anne-Marie Grewer speak to David Daleiden. (Center for Medical Progress)

In another case, Deborah VanDerhei, national director of the Consortium of Abortion Providers, was recorded saying that the organization advises clinics to think twice before accepting reimbursement for the cost of making fetal tissue donations possible.

In Daleiden's edited video, she says: "We're trying to figure this out as an industry about how we're going to manage remuneration, because the headlines would be a disaster."

Deleted is her preceding comment that clinics should facilitate tissue donation without financial reimbursement as part of their public health mission. She said: "If remuneration can be taken off the table at all, that would be great. Can we just provide this as sort of a mission-based piece?"

Alissa Greenberg, Jenny Manrique and Gabriel Sanchez contributed to this article.

About this story

This report is a collaboration between The Times and the Investigative Reporting Program (http://investigativereportingprogram.com), a nonprofit newsroom at the Graduate School of Journalism at UC Berkeley.

Video editing: Robert Meeks (https://twitter.com/robertmeeksrt). Produced by Lily Mihalik (https://twitter.com/mazet).

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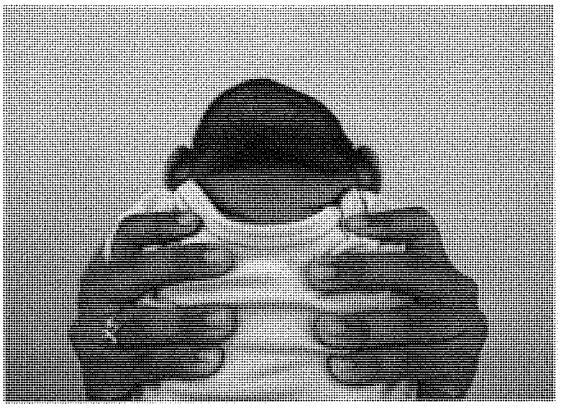

MACHO DOCT/REUTERS

Researchers are trying to establish whether Zika virus causes the birth defect microcephaly.

PUBLIC HEALTH

Zika highlights role of fetal-tissue research

Controversial tissue studies could prove crucial to probing link between virus and birth defects.

BY ERIKA CHECK HAYDEN

A protein that helps Zika virus infect adult skin cells might also give the virus access to stem cells that make brain cells, suggests a study carried out on donated human fetal tissue.

The result — published on 30 March in *Cell Stem Cell*[1] — is part of a growing body of research that seeks to determine how Zika might cause birth defects, but that requires a type of tissue that is increasingly controversial for researchers in the United States.

Recent advances in neuroscience and cell technology have given hints as to why some babies born to Zika-infected mothers have abnormally small heads — a condition called microcephaly — and other birth defects. But to fully understand what is happening in the womb, some scientists say that they need to study tissue from fetuses, which can be donated by couples who terminate pregnancies.

Researchers already knew that a protein called AXL enabled Zika to enter human skin cells. Now, Arnold Kriegstein, a neuroscientist at the University of California, San Francisco, (UCSF) and his colleagues show that the protein is also made by cells in the fetus that form the eyes and the brain. AXL could provide a means for Zika virus to infect these cells.

Two other studies published this month[2,3] showed that Zika specifically targets and kills neuron-forming cells, including those in organoids — brain-like structures derived from reprogrammed human skin cells. These studies suggest that Zika causes microcephaly by damaging fetal cells that make the brain, says neuroscientist Patricia Pestana Garcez of the Federal University of Rio de Janeiro, Brazil, who led one of the studies.

"Many fewer people are willing to donate, and it's slowing us down."

Kriegstein's study used fetal tissue donated by patients treated at UCSF medical facilities. But such material may get harder to come by, because the collection and use of fetal cells is under renewed scrutiny in the United States. Last July, an anti-abortion group called the Center for Medical Progress in Irvine, California, released video of employees from the non-profit health-care provider Planned Parenthood discussing the sale of fetal tissue from abortions for research. Members of the US House of Representatives are now investigating the use of fetal tissue in research.

Scientists in the United States worry that the controversy could hamper essential research on the Zika virus. "Many fewer people are willing to donate, and it's slowing us down," says Susan Fisher, a stem-cell and developmental biologist at UCSF.

Fisher is studying how Zika virus is transmitted from mother to baby. She has found AXL in fetal cells called trophoblasts that anchor the placenta, which supplies a fetus with blood and nutrients, to the mother's uterus. These cells are known to transmit infections such as cytomegalovirus from mother to baby. "This suggests that the placenta is extremely capable of transmitting Zika," says Fisher, whose studies rely on fetal tissue donated from terminated and full-term pregnancies.

Carolyn Coyne, a virologist at the University of Pittsburgh in Pennsylvania, says that fetal tissue is particularly crucial for studies of Zika because the virus seems to be able to harm a fetus throughout pregnancy[4]. "It is absolutely essential to study Zika infection in human fetal tissue," says Coyne. "These types of studies need to extend to all stages of pregnancy."

Because abortion is illegal or highly restricted in many Latin American countries, laboratory research on neural development in the regions hit hardest by Zika relies mainly on other types of human tissue, such as organoids. Researchers in Brazil, for example, are studying the lethality of different Zika viruses in neurons and organoids derived from cord blood.

Both Fisher and Kriegstein are planning further studies to test how Zika infects developing brain and placental cells. They argue that such studies are crucial to establish why the virus damages babies' brains, and whether this can be prevented.

The scientists will also use organoids and animal models, but they note that neither of these is a perfect substitute for human fetal tissue. For instance, researchers aren't sure how faithfully the growth of brain organoids replicates human brain development. "It'll be important to demonstrate in human tissue exactly how the virus is creating the pattern of damage that is emerging," Kriegstein says. "In situations like this, where there's considerable time pressure to try to unravel what's going on and to protect the developing human brain, it's especially important." ■

1. Nowakowski, T. J. *et al. Cell Stem Cell* http://dx.doi.org/10.1016/j.stem.2016.03.012 (2016).
2. Garcez, P. P. *et al. PeerJ Preprints* **4**, e1817v3 (2016).
3. Tang, H. *et al. Cell Stem Cell* http://dx.doi.org/10.1016/j.stem.2016.02.016 (2016).
4. Brasil, P. *et al. N. Eng. J. Med.* http://dx.doi.org/10.1056/NEJMoa1602412 (2016).

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From the Sacramento Business Journal:
http://www.bizjournals.com/sacramento/print-edition/2015/06/19/cate-dyer-founder-and-ceo-stem-express-llc.html

2015 Women Who Mean Business

Cate Dyer, founder and CEO, Stem Express

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Jun 19, 2015, 3:00am PDT **Updated: Aug 6, 2015, 10:57am PDT**

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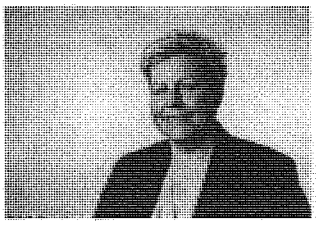

DENNIS MCCOY | SACRAMENTO BUSINESS JOURNAL

Cate Dyer, founder and CEO, Stem Express LLC

Cate Dyer wanted to do more to help patients. But caught up in the bustle of daily life and her job at a Bay Area bioscience company, she found herself postponing her dreams. Then she broke her leg in a fall down the stairs.

"It was the universe's way of shutting me down," she said. "It was then that I decided I should do something different."

Being sidelined gave Dyer a chance to formulate a plan. In March 2010, she launched **StemExpress LLC**, a company that provides human

blood, bone marrow and tissue to medical researchers.

By getting specimens to researchers more quickly and in larger quantities than was previously available, Dyer's work can shorten the length of a research study — from years to months in some cases. And that means new treatments may reach patients sooner.

She started StemExpress with just $9,000, running the business out of her Placerville home. She quickly found that there was indeed a demand for the company's products. Several new clients contacted her each week, without any active marketing, as word about StemExpress spread along the scientific grapevine.

The company ranked No. 363 last year on the Inc. 500 list of fastest-growing private companies, with 1,315 percent growth over three years and revenue of $2.2 million in 2013. And it ranked No. 35 on Inc.'s list of the fastest growing women-led companies in the country.

StemExpress has a spacious facility in Placerville that includes offices, a laboratory and a donor room. It's opening a branch in Washington, D.C., in the next three months and is looking at the possibility of a site in Europe as well. With a staff of 29, she expects to have more than 40 employees by the end of the year.

"What she's created is very impressive," said Rich Foreman, CEO of Apptology. "She's grown that to an amazingly solid business in the region."

Foreman said the achievement is even more noteworthy because Dyer "boot-strapped" the company, starting with a small amount of her own money rather than investor funds.

At the same time, Foreman said, Dyer has shown a commitment to her local community, where StemExpress has given an economic boost to Placerville and El Dorado County. Dyer could have moved the business to Silicon Valley, he noted.

But Dyer is committed to the Sacramento area. She is involved with the

Sacramento Regional Technology Alliance, participating in women-in-tech dinners, speaking as part of the "Succeeding in Sacramento" series and serving on the organization's MedStart CEO forum aimed at improving health care through technology. She's also a board member of the Sacramento Metro Chamber of Commerce.

Cary Adams, chairman of SARTA's MedStart, called Dyer a "valued member" of the CEO forum.

"Cate has found out how to make money and build a business in the regenerative-medicine space ... by meeting the research industry's ever-increasing demand for cord blood and similar products," Adams said. "By supplying that need more efficiently, Cate and StemExpress are helping to speed many new cures to market."

In 2003, when attending Santa Barbara Community College, Dyer planned to become an emergency medicine physician. To gain experience, she worked in the trauma center at Cottage Hospital in Santa Barbara. She later she graduated from California State University Sacramento with a degree in sociology, still planning to go to med school.

But she began to see flaws in the health care system and didn't think she could make much of a difference as a doctor.

"The more I worked in the emergency room, the less I was sure I wanted to be an emergency room physician," she said. "I realized I had to come at it a different way."

She also began to see flaws while working in tissue procurement at the Bay Area bioscience company. The problem: how the lack of human blood or tissue specimens was slowing down research.

For example, a scientist studying eye disease might turn to a transplant bank for human eye tissue, Dyer said. But the transplant bank only deals in healthy tissue; diseased tissue is more difficult to obtain.

StemExpress works with hospitals to procure human blood and tissue.

The company has clients worldwide; many are at major medical universities.

Dyer said StemExpress has had a number of buyout offers. So far, she has turned them down, concerned that a new owner would restrict the availability of StemExpress products.

Dyer said she would rather make the products widely available in order to foster healthy competition among researchers. "I want to fuel the research," she said.

The essentials

Age: 36
Education: A.A. in biology, Santa Barbara City College; B.A. in sociology, California State University Sacramento
Personal: Lives in Placerville; committed but unmarried; has a horse, a mule and two dogs
Advice to younger women: "Dream first, figure out the details as you go."
Biggest whoops: "Trusting people without merit."
Something about you that would surprise people: Majoring in sociology, rather than in a scientific field
A tough balancing act: Dyer said she finds it hard to say "no" to researchers who come to her with requests for a certain number of tissue samples in a tight timeframe. After all, the progress of medical research is at stake. Still, she carves out time to spend on her hobbies, riding horses or dirt bikes."It's a balance," she said. "It's tough."
Fantasy career: Country singer

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225-2927

Minority (202) 225-3641

May 11, 2016

Mr. Brian Lennon
Warner Norcross & Judd
111 Lyon Street, N.W.
Grand Rapids, MI 49503

Dear Mr. Lennon:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, April 20, 2016, to testify at the hearing entitled "The Pricing of Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, May 25, 2016. Your responses should be mailed to Rachel Collins, Investigative Counsel and Clerk, Select Investigative Panel of the Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Rachel.Collins@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Panel.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

The Honorable Janice D. Schakowsky, Ranking Member

1. **Assume that you conducted an investigation and concluded to your satisfaction that no one is profiting from fetal tissue that is made available as a consequence of a legal abortion and that all laws have been followed with regard to donation of that tissue for research purposes. Would you support use of that tissue for research purposes?**

   As a former federal prosecutor I was asked to review the provided exhibits and apply the information contained therein to various applicable evidentiary standards and the statute at issue. As I stated in both my written testimony and my oral statement, I am neither a medical ethicist nor a theologian, and I was not asked to testify on my personal beliefs regarding the use of fetal tissue in research. Nevertheless, I have no personal objection to the use of fetal tissue in research provided the tissue is obtained through naturally occurring stillborn births and miscarriages, with the informed consent of the parents, and through healthcare facilities in full compliance with state and federal law.

2. **If you answered no to the first question—or otherwise qualified your response in any manner—are there any circumstances for which you would allow fetal tissue research?**

   Fetal tissue can be made available to researchers as a result of naturally occurring stillborn births and miscarriages, which in my opinion is very different than the intentional creation of fetal tissue through abortion. Assuming the parents of such children knowingly (*i.e.*, with informed consent) donate this stillborn or miscarried fetal tissue to research and the healthcare facilities involved are otherwise complying with state and federal law, I personally have no objection to the use of fetal tissue for research purposes.

3. **Prominent researchers have highlighted the need for fetal tissue to study and address the impact of the Zika virus on fetal brain development. For example, a leading researcher at the University of Pittsburgh Medical Center recently confirmed that "It is absolutely essential to study Zika infection in human fetal tissue."[1] Assuming, once again, that all laws related to fetal tissue donation have been followed, would you support the use of fetal tissue as part of research efforts to analyze and understand the Zika virus? To possibly help identify a cure?**

   Again, assuming the fetal tissue was acquired from naturally occurring stillborn births and/or miscarriages, and assuming the parents of these children knowingly (*i.e.*, with informed consent) donated this fetal tissue and the healthcare facilities involved otherwise complied with the law, I have no objection to the use of such fetal tissue for research on the Zika virus or any other legitimate research purpose.

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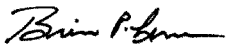
[1] Erika Check Hayden, *Zika highlights role of controversial fetal-tissue research*, NATURE (Mar. 30, 20 16).

Respectfully submitted,



Brian Patrick Lennon

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Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515–6115

Majority (202) 225-2927

Minority (202) 225–3641

May 11, 2016

Mr. Michael J. Norton
Thomas N. Scheffel & Associates, P.C.
3801 East Florida Avenue
Suite 600
Denver, CO 80210

Dear Mr. Norton:

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Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

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JEFFERY L. WEIDEN
LENNY A. BEST
****MICHAEL J. NORTON

May 13, 2016

[redacted]

Honorable Marsh Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515-6115

Dear Madam Chairman:

In your May 11, 2016 letter, you ask that I answer three questions which I understand to have been posed to me by the Honorable Janice D. Schakowsky, Ranking Member of the Select Investigative Panel.

These questions, as well as their answers, are irrelevant to issues being considered by the Select Investigative Panel at its April 20, 2016 hearing. Indeed, these questions should be irrelevant to any competent, impartial federal prosecutor in determining whether or not there should be, in any case, a criminal investigation and/or prosecution. That other evils, perceived or real, should be solved by violating one of our Nation's criminal laws would result in anarchy.

As proclaimed by the United States Supreme Court in *Berger v. United States,* 295 U.S. 78, 88 (1935):

> The [prosecutor] is the representative not of an ordinary party to a controversy, but of a sovereignty whose obligation to govern impartially is as compelling as its obligation to govern at all; and whose interest, therefore, in a criminal prosecution is not that it shall win a case, but that justice shall be done. As such, he is in a peculiar and very definite sense the servant of the law, the twofold aim of which is that guilt shall not escape or innocence suffer. He may prosecute with earnestness and vigor - indeed, he should do so. But, while he may strike hard blows, he is not at liberty to strike foul ones. It is as much his duty to refrain from improper

> methods calculated to produce a wrongful conviction as it is to use every legitimate means to bring about a just one

Every federal prosecutor I have known is familiar with this Supreme Court declaration and takes it, and the prosecutor's oath of office to, among other things, support and defend the Constitution of the United States very seriously.

With the foregoing in mind, prior to my April 20, 2016 appearance before the Select Investigative Panel, the Select Investigative Panel asked me to opine whether, based on my experience as United States Attorney for the District of Colorado, I believed there to be sufficient credible evidence upon which to determine that there was probable cause to believe that the provisions of 42 U.S.C. § 289g-2 had been violated and, if so, what, if any, steps would I thereupon take.

The relevant statute is quite clear – the central question is whether anyone has profited from the sale of hearts, brains, livers, and other organs harvested from aborted babies. It seems clear from the documents and evidence that the Select Investigative Panel had gathered and made available to me prior to April 20, 2016, as well as the videos other materials I have previously reviewed, that there has been profiteering at multiple levels in this business.

During my testimony and in the answers to questions from Members of the Select Investigative Panel, here is what I attempted to communicate during the brief time I had to present my testimony:

1. A competent, impartial federal prosecutor would, with the help of competent federal criminal investigators, start by analyzing the elements of the offense as set forth in the relevant federal statute. Here, the statute prohibits the harvesting and trafficking of fetal body parts for profit, and provides for criminal penalties (a fine and/or imprisonment) for those who knowingly do so.

2. A competent, impartial federal prosecutor would, with the help of competent federal criminal investigators, then take time to view the videos, both the complete videos and the edited versions of the videos, which had been released by the Center for Medical Progress[1] to determine what the videos in fact depict.

3. These videos, which I have reviewed, depict that selected abortion clinics in, among other states, California, Colorado, and Texas, have admitted to making money by harvesting and trafficking the hearts, brains, lungs, eyes and livers of aborted babies. In addition, the videos and the evidence provided to me by the staff of the Select Investigative Committee prior to the April 20, 2016 hearing, further depict that there is a middleman procurement business involved which buys these organs from aborted babies from the abortion clinic and then sells them to others, including research universities. The values assigned by the abortion clinics and the middleman procurement business almost certainly evidence that there was a profit in these transactions.

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[1] These videos have been available at the Center for Medical Progress's website at http://www.centerformedicalprogress.org/cmp/investigative-footage/

4. One of these videos depicts Planned Parenthood Federation of America executive Deborah Nucatola discussing prices for the body parts of aborted babies and stating that Planned Parenthood's abortionists would alter abortion procedures in order to further Planned Parenthood's organ harvesting and trafficking program. These statements appear to be admissions of violations of an element of the relevant criminal statute, *i.e.*, the prohibition against any "alteration of the timing, method, or procedures used to terminate the pregnancy ... solely for the purposes of obtaining the tissue." 42 U.S.C. § 289g-1(c)(4).

5. To refute claims by potential subjects of the criminal investigation that the edited versions of the videos released by the Center for Medical Progress had been so "highly edited as to be unreliable," a competent, impartial federal prosecutor would then engage the services of a forensic analyst to determine if these claims by potential subjects of the criminal investigation had merit. As I testified on April 20, 2016, on Monday, September 28, 2015, such a forensic analysis, prepared by Coalfire Systems, a highly accredited forensic analyst and cybersecurity firm, released its report which demonstrated that the edited versions of the undercover videos released by the Center for Medical Progress showed no evidence of manipulation or "heavy" editing as had been alleged so as to make those edited videos misleading or unreliable. In any event, the unedited versions of the videos, not the shorter edited versions, would be relied upon by a competent, impartial federal prosecutor.

6. In my opinion, based on the foregoing, a competent, impartial federal prosecutor would, with the help of competent federal criminal investigators, would thereupon determine that what was depicted on the complete videos released by the Center for Medical Progress constituted probable cause to believe that the provisions of 42 U.S.C. § 289g-2 had been violated. As a result, a competent, impartial federal prosecutor would thereupon open a federal Grand Jury investigation into these apparent federal crimes. Search warrants, subpoenas, and Grand Jury testimony would be sought and presented. Putative defendants would include, among others, the abortion clinics and the middleman procurement business(es) involved in the harvesting and sale of body parts of aborted babies.

7. Because the details of payments, expenses, costs, and persons involved with any of the actions or monetary transfers would be indispensable in proving that the relevant statute had been violated, it is my further opinion, based on the foregoing, that a competent, impartial federal prosecutor would, with the help of competent federal criminal investigators, cause federal Grand Jury subpoenas to be issued to, among others, these putative defendants and to those entities which ultimate acquire the body parts of aborted babies for financial records from which it could be determined what, if any, profit any of these entities made from the sale of body parts of aborted babies.

8. Should this federal Grand Jury investigation lead a competent, impartial federal prosecutor to conclude that the provisions of 42 U.S.C. § 289g-2 had been violated, a competent, impartial federal prosecutor would thereupon present a proposed indictment to a federal Grand Jury. Should the federal Grand Jury vote to return the indictment,

the indictment would then be pursued as any other federal criminal charge was pursued.

What should be ignored by a competent, impartial federal prosecutor are protestations of innocence by the subjects of a criminal investigation. Thus, a self-serving letter from a potential subject that asserts that the potential subject has not violated any federal law, is meaningless.

What should also be ignored by a competent, impartial federal prosecutor is the fact that the subjects of a federal criminal investigation are politically well-connected. It would make a mockery of our federal criminal justice system to investigate and prosecute those who do not have friends in high places while, at the same time, declining to investigate and prosecute those who do have friends who hold high elective office in our Nation.

What should be recognized is that it is irrelevant that those involved with the Centers for Medical Progress surreptitiously obtained the undercover videos without the knowledge of the subjects of the investigation. Similar methods are regularly used by undercover law enforcement officers. The "facts" on the videos speak for themselves.

What should also be recognized is that, once it became known that a federal criminal investigation was underway, it is highly likely that key witnesses would come forward, either voluntarily or with immunity agreements, to provide corroborating testimony.

Likewise, the answers to the three questions posed by the Honorable Janice D. Schakowsky are also irrelevant to a competent, impartial federal prosecutor. Nevertheless, for what it is worth, my answers to these three questions are as follows:

1. **Assume that you conducted an investigation and concluded to your satisfaction that no one is profiting from fetal tissue that is made available as a consequence of a legal abortion and that all laws have been followed with regard to donation of that tissue for research purposes. Would you support use of that tissue for research purposes?**

   My Answer: No.

2. **If you answered no to the first question – or otherwise qualified your response in any manner – are there any circumstances for which you would allow fetal tissue research?**

   My Answer: No.

3. **Prominent researchers have highlighted the need for fetal tissue to study and address the impact of the Zika virus on fetal brain development. For example, a leading researcher at the University of Pittsburgh Medical Center recently confirmed that "It is absolutely essential to study Zika infection in human fetal tissue." Assuming, once again, that all laws related to fetal tissue donation have**

been followed, would you support the use of fetal tissue as part of research efforts to analyze and understand the Zika virus? To possibly help identify a cure?

My Answer: No.

Thank you for your courtesy during the April 20, 2016 hearing. It has been a distinct honor to have been asked to participate in this important investigation. If I may be of further service to you or to the Select Investigation Panel, please do not hesitate to let me know.

Sincerely,

s/ *Michael J. Norton*

Michael J. Norton

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225-2927

Minority (202) 225-3641

May 11, 2016

Ms. Catherine Glenn Foster
Charlotte Lozier Institute
1200 New Hampshire Avenue, N.W.
Suite 750
Washington, DC 20036

Dear Ms. Foster:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, April 20, 2016, to testify at the hearing entitled "The Pricing of Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, May 25, 2016. Your responses should be mailed to Rachel Collins, Investigative Counsel and Clerk, Select Investigative Panel of the Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Rachel.Collins@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Panel.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

CHARLOTTE LOZIER INSTITUTE
The education and research arm of the Susan B. Anthony List

June 3, 2016

Re: The Pricing of Fetal Tissue: Additional Questions for the Record
Responses from Catherine Glenn Foster

The Honorable Janice D. Schakowsky

1. **Assume that you conducted an investigation and concluded to your satisfaction that no one is profiting from fetal tissue that is made available as a consequence of a legal abortion and that all laws have been followed with regard to donation of that tissue for research purposes. Would you support use of that tissue for research purposes?**

Even if abortion clinics and middleman procurement businesses adhered to current law on trading in babies' body parts and on women's medical privacy HIPAA rights, I could not endorse the use of human fetal tissue for research purposes. Using the bodies of babies who were intentionally terminated is simply too risky, for both women and children. As a woman, and especially as a post-abortive woman, I know that women deserve better than the assembly-line process of signing our rights away I encountered even at a so-called "nice" abortion clinic. Even if abortion clinics and middleman procurement businesses followed the letter of the law, they would still be operating in a system that objectifies women and our children and treats our bodies as profit centers. The system incentivizes selective information, coercion, and duress, in industrialized centers that use abortions to procure raw material in a process that strips women of our privacy. And we as a society must afford aborted children the minimal dignity that comes with not having their remains further picked through to be bought and sold like chattel. Despite clinics' use of clinical terms, we are in fact talking about real and unique human beings whose lives were tragically snuffed out. Abortion clinics have admitted that disposal of these aborted babies' bodies is a real problem for them, and so selling the bodies is a triple windfall: the clinic is paid for the abortion, receives money from the procurement business for minimal if any effort, and is then spared paying for disposal of the aborted babies. And the clinics have also admitted that when it comes to the market in baby body parts, they're more interested in looking like they follow the law than actually following the law - just as one clinic responded to evidence of financial waste and abuse by covering its tracks, saying: "We're going to

hope we don't get caught." Even if a clinic actually followed the letter of the law, common sense and common decency prohibit any market in aborted babies' organs.

2. **If you answered no to the first question – or otherwise qualified your response in any manner – are there any circumstances for which you would allow fetal tissue research?**

Yes, I believe that a mother who has experienced a miscarriage or stillbirth should have the opportunity to donate her child's body for medical research purposes and potentially allow that child's too-brief life to resonate through generations and save the lives of others. However, I would continue to advocate for strengthening the oversight process and preserve the respect due a fellow human being even in these limited circumstances.

3. **Prominent researchers have highlighted the need for fetal tissue to study and address the impact of the Zika virus on fetal brain development. For example, a leading researcher at the University of Pittsburgh Medical Center recently confirmed that "It is absolutely essential to study Zika infection in human fetal tissue." Assuming, once again, that all laws related to fetal tissue donation have been followed, would you support the use of fetal tissue as part of research efforts to analyze and understand the Zika virus? To possibly help identify a cure?**

Scientists from numerous esteemed academic institutions are very successfully researching the effects of the Zika virus on developing human brain cells without using aborted fetal tissue. For example, this year in the leading research journal Cell Stem Cell, researchers from Florida State, Johns Hopkins, and Emory published their work *Zika Virus Infects Human Cortical Neural Progenitors and Attenuates Their Growth*, in which they describe their success in developing a model system demonstrating that Zika can infect and damage some developing brain cells. The model, which the authors note can be used to "investigate the impact and mechanism of [Zika] on human brain development and provide a platform to screen therapeutic compounds," was developed with Nobel Prize-winning, ethically sourced human induced pluripotent stem cells, rather than tissues from aborted babies. A recent Brazilian study, *Zika Virus Impairs Growth in Human Neurospheres and Brain Organoids*, likewise used groundbreaking hiPSCs in its confirmation that developing human brain cells are susceptible to infection and damage by the Zika virus. And we know that modern vaccine development is not based on fetal tissue. For example, scientists recently achieved 100% protection in tests of a vaccine for the Zika-related Dengue virus; this vaccine was developed using monkey cells and a mosquito cell line. However, I do believe that a mother who has experienced a miscarriage or stillbirth should have the opportunity to donate her child's body.

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

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COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515–6115

Majority (202) 225–2927

Minority (202) 225–3641

May 11, 2016

Mr. Kenneth Sukhia
Sukhia Law Group
902 N. Gadsden Street
Tallahassee, FL 32303

Dear Mr. Sukhia:

Thank you for appearing before the Select Investigative Panel of the Committee on Energy and Commerce on Wednesday, April 20, 2016, to testify at the hearing entitled "The Pricing of Fetal Tissue."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Panel.

Sincerely,

Marsha Blackburn
Chairman
Select Investigative Panel of
the Committee on Energy and Commerce

cc: Janice D. Schakowsky, Ranking Member, Select Investigative Panel of the Committee on Energy and Commerce

Attachment

Attachment — Additional Questions for the Record

The Honorable Janice D. Schakowsky

During the April 20, 2016 Select Investigative Panel hearing, you were asked by several Republican Members to speculate about possible violation of 42 U.S.C. § 289g–2 based on "exhibits" created by the Majority staff. Those documents were provided to hearing witnesses and the press prior to the hearing. However, Republicans refused to provide the documents to the "procurement business" that were the alleged source of some of their materials and staff-created work product. Democratic Members repeatedly objected to the legitimacy of the materials and their use at the hearing.

The hearing only contained minimal discussion regarding the value of and the witnesses' viewpoints on the use of fetal tissue for research purposes.

1. Assume that you conducted an investigation and concluded to your satisfaction that no one is profiting from fetal tissue that is made available as a consequence of a legal abortion and that all laws have been followed with regard to donation of that tissue for research purposes. Would you support use of that tissue for research purposes?

   I do not have an opinion on the scientific utility of using fetal tissue for research purposes because the efficacy of such research is beyond my legal expertise. I do not believe fetal research has ever led to the cure of any diseases. I do know it is against the law to make a profit from the distribution of such tissue and that there is sufficient evidence to justify an investigation in this case.

2. If you answered no to the first question – or otherwise qualified your response in any manner – are there any circumstances for which you would allow fetal tissue research? (See above).

3. Prominent researchers have highlighted the need for fetal tissue to study and address the impact of the Zika virus on fetal brain development. For example, a leading researcher at the University of Pittsburgh Medical Center recently confirmed that "It is absolutely essential to study Zika infection in human fetal tissue."[1] Assuming, once again, that all laws related to fetal tissue donation have been followed, would you support the use of fetal tissue as part of research efforts to analyze and understand the Zika virus? To possibly help identify a cure? (See above).

[1] Erika Check Hayden, *Zika highlights role of controversial fetal-tissue research*, NATURE (Mar. 30, 2016).

○